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Chapter 45-A - Speech Generating Devices

View Attachments

Chapter 45-A contains the medical policy for speech generating devices. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Speech Generating Devices

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

K0541	Speech generating device, digitized speech, using pre-recorded messages, less than or equal to 8 minutes recording time
K0542	Speech generating device, digitized speech, using pre-recorded messages, greater than 8 minutes recording time
K0543	Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device
K0544	Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access
K0545	Speech generating software program, for personal computer or personal digital assistant
K0546	Accessory for speech generating device, mounting system
K0547	Accessory for speech generating device, not otherwise classified.

HCPCS MODIFIER:

KX:	Specific required documentation on file.

BENEFIT CATEGORY: Durable Medical Equipment

REFERENCE: Coverage Issues Manual 60-9, 60-23

DEFINITIONS:

Speech generating devices (SGDs) are defined as speech aids that provide individuals with severe speech impairment the ability to meet their functional speaking needs.

Speech-language pathologists (SLPs) are licensed health professionals educated at the graduate level in the study of human communication, its development and its disorders. The SLP must hold a Certificate of Clinical Competence (CCC) in speech-language pathology from the American Speech-Language-Hearing Association.

Digitized speech (K0541, K0542), sometimes referred to as devices with "whole message" speech output, utilize words or phrases that have been recorded by an individual other than the SGD user for playback upon command of the SGD user.

Synthesized speech (K0543, K0544), unlike the pre-recorded messages of digitized speech, is a technology that translates a user's input into device-generated speech. Users of synthesized speech SGDs are not limited to pre-recorded messages but rather can independently create messages as their communication needs dictate.

K0543 devices require that the user make physical contact with a keyboard, touch screen or other display containing letters.

K0544 devices permit the user multiple methods of message formulation and multiple methods of device access. Multiple methods of message formulation must include the capability for message selection by two or more of the following methods: letters, words, pictures or symbols. Multiple methods of access must include the capability to access the device by two or more of the following: direct physical contact with a keyboard or touch screen, indirect selection techniques with a specialized access device such as a joystick, head mouse, optical head pointer, switch, light pointer, infrared pointer, scanning device, or Morse Code.

Speech generating software programs (K0545) enable a laptop computer, desktop computer or personal digital assistant (PDA) to function as an SGD. Within this policy, the term SGD also describes these speech generating software programs.

Personal digital assistants (PDAs) are handheld devices that integrate the functions of a small computer with features such as a cell phone, personal

organizer, electronic mail or pager. Information may be input via a pen-based system using a stylus and handwriting recognition software, keyboard or downloaded from a personal computer using special cables and software.

Mounting systems (K0546) are devices necessary to place the SGD device, switches and other access devices within the reach of the patient.

Accessories for speech generating devices (K0547) include, but are not limited to, access devices that enable selection of letters, words or symbols via direct or indirect selection techniques. Examples of access devices include, but are not limited to, optical head pointers, joysticks, switches, wheelchair integration devices and SGD scanning devices. In addition, replacement accessories such as batteries, battery chargers and AC adapters are included in this code.

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.
A speech generating device (K0541 - K0545) is covered when all of the following criteria (1-7) are met:

1. Prior to the delivery of the SGD, the patient has had a formal evaluation of their cognitive and communication abilities by a speech-language pathologist (SLP). The formal, written evaluation must include, at a minimum, the following elements:
a) current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment;
b) an assessment of whether the individual's daily communication needs could be met using

other natural modes of communication;

c) a description of the functional communication goals expected to be achieved and

treatment options;

d) rationale for selection of a specific device and any accessories;
e) demonstration that the patient possesses treatment plan that includes a training schedule for the selected device;
f) the cognitive and physical abilities to effectively use the selected device and any accessories to communicate;
g) for a subsequent upgrade to a previously issued SGD, information regarding the functional benefit to the patient of the upgrade compared to

the initially provided SGD; and,
2. The patient's medical condition is one resulting in a severe expressive speech impairment; and,
3. The patient's speaking needs cannot be met using natural communication methods; and,
4. Other forms of treatment have been considered and ruled out; and,
5. The patient's speech impairment will benefit from the device ordered; and,
6. A copy of the SLP's written evaluation and recommendation have been forwarded to the patient's
treating physician prior to ordering the device; and,
7. The SLP performing the patient evaluation may not be an employee of or have a financial
relationship with the supplier of the SGD.

If one or more of the SGD coverage criteria 1-7 is not met, the SGD will be denied as not medically necessary.

Codes K0541 - K0544 and code K0545 perform the same essential function - speech generation. Therefore, claims for more than one SGD will be denied as not medically necessary.

Laptop computers, desktop computers, PDAs or other devices that are not dedicated SGDs are noncovered because they do not meet the definition of durable medical equipment (DME).

Software (K0545) that enables a laptop computer, desktop computer or PDA to function as an SGD is covered as an SGD; however, installation of the program or technical support are not separately reimbursable.

Accessories

Accessories (K0547) for K0541 - K0544 are covered if the basic coverage criteria (1-7) for the base device are met and the medical necessity for each accessory is clearly documented in the formal evaluation by the SLP.

CODING GUIDELINES:

Code E1900 (Synthesized speech augmentative communication device with dynamic
display), effective for dates of service on or after the effective date of this policy, is no longer valid for submission to the DMERC.

Codes K0541 and K0542 must be used to code devices that generate only digitized speech output. Codes K0543 and K0544 must be used to code devices that generate synthesized speech. Devices that have the capability to generate both digitized and synthesized speech must be coded K0543 or K0544, depending on the method of synthesized speech formulation and device access.

Codes K0541 - K0544 include the device, any applicable software,

batteries, battery chargers, and AC adapters. These items may not be billed separately.

Code K0545 is used to code for a speech generating software program that enables a laptop computer, desktop computer or personal digital assistant (PDA) to function as an SGD. The allowance for code K0545 includes the speech generating software program only. Installation of the program or technical support must not be billed separately. Code K0545 must not be used to code software included with the initial provision of the SGD (K0541 - K0544) since the software cost is included in the reimbursement for those SGD codes. In addition, code K0545 must not be used to code software included with the initial provision of the access device (K0547) since the software cost is included in the reimbursement for the access device.

Upgrades to K0545 are subsequent versions of a speech generating software program that may include enhanced features or other improvements. Upgrades to K0545 must be coded K0545.

Mounting systems necessary to place the SGD device, switches and other access devices within the reach of the patient must be coded K0546.

Accessories to SGDs such as access devices should be coded K0547. There should be no separate billing of any software, interfaces, cables, adapters, interconnects, or switches necessary for the accessory to interface with the SGD (K0541 - K0545).

Upgrades to K0541 - K0544 are subsequent versions of the device's software program or memory modules that may include enhanced features or other improvements. Upgrades to K0541 - K0544 must be coded K0547.

Suppliers should refer to the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) web site or contact the SADMERC for guidance on the correct coding for these devices.

DOCUMENTATION:

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the SGD and all accessories must be signed and dated by the treating physician and kept on file by the supplier. For codes K0541 - K0547, if all of the coverage criteria for these devices specified in the Coverage and Payment Rules section of the policy have been met, and if the

supplier has a copy of the required SLP evaluation, a KX modifier should be added to the code. A KX modifier must not be used if any of the requirements listed above are not met.

When billing codes K0545 - K0547, the claim must include documentation indicating the brand name and model name/number of the item provided. This information must be included with the claim if submitted hard copy or transcribed into the HA0 record of an electronic claim.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after July 1, 2002.

This is a revision to a previously published policy.

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MEDICAL POLICY

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    f) the cognitive and physical abilities to effectively use the selected device and any accessories to communicate;
    g) for a subsequent upgrade to a previously issued SGD, information regarding the functional benefit to the patient of the upgrade compared to the initially provided SGD; and,
2. The patient's medical condition is one resulting in a severe expressive speech impairment; and,
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5. The patient's speech impairment will benefit from the device ordered; and,
6. A copy of the SLP's written evaluation and recommendation have been forwarded to the patient's treating physician prior to ordering the device; and,
7. The SLP performing the patient evaluation may not be an employee of or have a financial relationship with the supplier of the SGD.

If one or more of the SGD coverage criteria 1-7 is not met, the SGD will be denied as not medically necessary.

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Accessories

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Codes K0541 - K0544 include the device, any applicable software, batteries, battery chargers, and AC adapters. These items may not be billed separately.

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When billing codes K0545 - K0547, the claim must include documentation indicating the brand name and model name/number of the item provided. This information must be included with the claim if submitted hard copy or transcribed into the HA0 record of an electronic claim.

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Chapter 50 - Refractive Lenses

View Attachments

Chapter 50 contains the medical policy for refractive lenses. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Refractive Lenses

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

Frames

V2020	Frames, purchases
V2025	Deluxe frame

Eyeglass Lenses

V2100	Sphere, single vision, plano to plus or minus 4.00D, per lens
V2101	Sphere, single vision, plus or minus 4.12Dto plus or minus 7.00D, per lens
V2102	Sphere, single vision, plus or minus 7.12D to plus or minus 20.00D, per lens
V2103	Spherocylinder, single vision, plano to plus or minus 4.00D sphere, .12 to 2.00D cylinder, per lens
V2104	Spherocylinder, single vision, plano to plus or minus 4.00D sphere, 2.12 to 4.00D cylinder, per lens

V2105	Spherocylinder, single vision, plano to plus or minus 4.00D sphere, 4.25 to 6.00D cylinder, per lens
V2106	Spherocylinder, single vision, plano to plus or minus 4.00D sphere, over 6.00D cylinder, per lens
V2107	Spherocylinder, single vision, plus or minus 4.25D to plus or minus 7.00D sphere, .12 to 2.00D cylinder, per lens
V2108	Spherocylinder, single vision, plus or minus 4.25D to plus or minus 7.00D sphere, 2.12 to 4.00D cylinder, per lens
V2109	Spherocylinder, single vision, plus or minus 4.25D to plus or minus 7.00D sphere, 4.25 to 6.00D cylinder, per lens
V2110	Spherocylinder, single vision, plus or minus 4.25 to 7.00D sphere, over 6.00D cylinder, per lens
V2111	Spherocylinder, single vision, plus or minus 7.25D to plus or minus 12.00D sphere, .25 to 2.25D cylinder, per lens
V2112	Spherocylinder, single vision, plus or minus 7.25D to plus or minus 12.00D sphere, 2.25D to 4.00D cylinder, per lens
V2113	Spherocylinder, single vision, plus or minus 7.25D to plus or minus 12.00D sphere, 4.25 to 6.00D cylinder, per lens
V2114	Spherocylinder, single vision, sphere over plus or minus 12.00D, per lens
V2115	Lenticular, (myodisc), per lens, single vision
V2116	Lenticular lens, non-aspheric, per lens, single vision
V2117	Lenticular, aspheric, per lens, single vision
V2118	Aniseikonic lens, single vision
V2199	Not Otherwise Classified, single vision lens
V2200	Sphere, bifocal, plano to plus or minus 4.00D, per lens
V2201	Sphere, bifocal, plus or minus 4.12D to plus or minus 7.00D, per lens
V2202	Sphere, bifocal, plus or minus 7.12D to plus or minus 20.00D, per lens
V2203	Spherocylinder, bifocal, plano to plus or minus 4.00D sphere, .12 to 2.00D cylinder, per lens
V2204	Spherocylinder, bifocal, plano to plus or minus 4.00D sphere, 2.12 to 4.00D cylinder, per lens
V2205	Spherocylinder, bifocal, plano to plus or minus 4.00D sphere, 4.25 to 6.00D cylinder, per lens
V2206	Spherocylinder, bifocal, plano to plus or minus 4.00D sphere, over 6.00D cylinder, per lens
V2207	Spherocylinder, bifocal, plus or minus 4.25D to plus or minus 7.00D sphere, .12 to 2.00D cylinder, per lens
V2208	Spherocylinder, bifocal, plus or minus 4.25D to plus or minus 7.00D sphere, 2.12 to 4.00D cylinder, per lens

V2209	Spherocylinder, bifocal, plus or minus 4.25D to plus or minus 7.00D sphere, 4.25 to 6.00D cylinder, per lens
V2210	Spherocylinder, bifocal, plus or minus 4.25D to plus or minus 7.00D sphere, over 6.00D cylinder, per lens
V2211	Spherocylinder, bifocal, plus or minus 7.25D to plus or minus 12.00D sphere, .25 to 2.25D cylinder, per lens
V2212	Spherocylinder, bifocal, plus or minus 7.25D to plus or minus 12.00D sphere, 2.25 to 4.00D cylinder, per lens
V2213	Spherocylinder, bifocal, plus or minus 7.25D to plus or minus 12.00D sphere, 4.25 to 6.00D cylinder, per lens
V2214	Spherocylinder, bifocal, sphere over plus or minus 12.00D, per lens
V2215	Lenticular (myodisc), per lens, bifocal
V2216	Lenticular, non-aspheric, per lens, bifocal
V2217	Lenticular, aspheric lens, bifocal
V2218	Aniseikonic, per lens, bifocal
V2219	Bifocal seg width over 28mm
V2220	Bifocal add over 3.25D
V2299	Specialty bifocal (by report)
V2300	Sphere, trifocal, plano to plus or minus 4.00D, per lens
V2301	Sphere, trifocal, plus or minus 4.12D to plus or minus 7.00D per lens
V2302	Sphere, trifocal, plus or minus 7.12D to plus or minus 20.00D, per lens
V2303	Spherocylinder, trifocal, plano to plus or minus 4.00D sphere, .12-2.00D cylinder, per lens
V2304	Spherocylinder, trifocal, plano to plus or minus 4.00D sphere, 2.25-4.00D cylinder, per lens
V2305	Spherocylinder, trifocal, plano to plus or minus 4.00D sphere, 4.25 to 6.00D cylinder, per lens
V2306	Spherocylinder, trifocal, plano to plus or minus 4.00D sphere, over 6.00D cylinder, per lens
V2307	Spherocylinder, trifocal, plus or minus 4.25D to plus or minus 7.00D sphere,.12 to 2.00D cylinder, per lens
V2308	Spherocylinder, trifocal, plus or minus 4.25D to plus or minus 7.00D sphere, 2.12 to 4.00D cylinder, per lens
V2309	Spherocylinder, trifocal, plus or minus 4.25D to plus or minus 7.00D sphere, 4.25 to 6.00D cylinder, per lens
V2310	Spherocylinder, trifocal, plus or minus 4.25D to plus or minus 7.00D sphere, over 6.00D cylinder, per lens
V2311	Spherocylinder, trifocal, plus or minus 7.25D to plus or minus 12.00D sphere, .25 to 2.25D cylinder, per lens

V2313	Spherocylinder, trifocal, plus or minus 7.25D to plus or minus 12.00D sphere, 4.25 to 6.00D cylinder, per lens
V2314	Spherocylinder, trifocal, sphere over plus or minus 12 .00D, per lens
V2315	Lenticular, (myodisc), per lens, trifocal
V2316	Lenticular non-aspheric, per lens, trifocal
V2317	Lenticular, aspheric lens, trifocal
V2318	Aniseikonic lens, trifocal
V2319	Trifocal seg width over 28 mm
V2320	Trifocal add over 3.25D
V2399	Specialty trifocal (by report)
V2410	Variable asphericity lens, single vision, full field, glass or plastic, per lens
V2430	Variable asphericity lens, bifocal, full field, glass or plastic, per lens
V2499	Variable sphericity lens, other type

Contact Lenses

V2500	Contact lens, PMMA, spherical, per lens
V2501	Contact lens, PMMA, toric or prism ballast, per lens
V2502	Contact lens, PMMA, bifocal, per lens
V2503	Contact lens, PMMA, color vision deficiency, per lens
V2510	Contact lens, gas permeable, spherical, per lens
V2511	Contact lens, gas permeable, toric, prism ballast, per lens
V2512	Contact lens, gas permeable, bifocal, per lens
V2513	Contact lens, gas permeable, extended wear, per lens
V2520	Contact lens, hydrophilic, spherical, per lens
V2521	Contact lens, hydrophilic, toric, or prism ballast, per lens
V2522	Contact lens, hydrophilic, bifocal, per lens
V2523	Contact lens, hydrophilic, extended wear, per lens
V2530	Contact lens, scleral, gas impermeable, per lens
V2531	Contact lens, scleral, gas permeable, per lens
V2599	Contact lens, other type

Low Vision Aids

V2600	Hand held low vision aids and other non-spectacle mounted aids
V2610	Single lens spectacle mounted low vision aids

V2615	Telescopic and other compound lens system, including distance vision telescopic, near vision telescopes and compound microscopic lens system

Miscellaneous

V2700	Balance lens, per lens
V2710	Slab off prism, glass or plastic, per lens
V2715	Prism, per lens
V2718	Press-on lens, Fresnell prism, per lens
V2730	Special base curve, glass or plastic, per lens
V2740	Tint, plastic, rose 1 or 2 per lens
V2741	Tint, plastic, other than rose 1or 2, per lens
V2742	Tint, glass, rose 1 or 2, per lens
V2743	Tint, glass, other than rose 1 or 2, per lens
V2744	Tint, photochromatic, per lens
V2750	Anti-reflective coating, per lens
V2755	U-V lens, per lens
V2760	Scratch resistant coating, per lens
V2770	Occluder lens, per lens
V2780	Oversize lens, per lens
V2781	Progressive lens, per lens
V2799	Vision service, miscellaneous

HCPCS Modifier:

KX	Specific required documentation on file
LT	Left side
RT	Right side

BENEFIT CATEGORY: Prosthetic Device

DEFINITIONS:

Aphakia is the absence of the lens of the eye.

Pseudophakia is an eye in which the natural lens has been replaced with an artificial intra-ocular lens (IOL).

Photochromatic lenses are those in which the degree of tint changes in response to changes in ambient light.

Progressive lens (V2781) is a multifocal lens that gradually changes in lens power from the top to the bottom of the lens, eliminating the line(s) that would otherwise be seen in a bifocal or trifocal lens.

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.

Refractive lenses are covered when they are medically necessary to restore the vision normally provided by the natural lens of the eye of an individual lacking the organic lens because of surgical removal or congenital absence. Covered diagnoses are limited to pseudophakia (ICD-9 V43.1), aphakia (ICD-9 379.31), and congenital aphakia (ICD-9 743.35). Lenses provided for other diagnoses will be denied as non-covered.

After each cataract surgery with insertion of an intraocular lens (ICD-9 V43.1), coverage is limited to one pair of eyeglasses or contact lenses. Replacement frames, eyeglass lenses and contact lenses are non-covered. If a beneficiary has a cataract extraction with IOL insertion in one eye, subsequently has a cataract extraction with IOL insertion in the other eye, and does not receive eyeglasses or contact lenses between the two surgical procedures, Medicare covers only one pair of eyeglasses or contact lenses after the second surgery. If a beneficiary has a pair of eyeglasses, has a cataract extraction with IOL insertion, and receives only new lenses but not new frames after the surgery, the benefit would not cover new frames at a later date (unless it follows subsequent cataract extraction in the other eye).

Tints (V2740 - V2744), anti-reflective coating (V2750), or oversize lenses (V2780) are covered only when they are medically necessary for the individual patient and the medical necessity is documented by the treating physician. When these features are provided as a patient preference item and are billed without a KX modifier (see Documentation section), they will be denied as not medically necessary.

U-V lenses (V2755) are considered reasonable and necessary following cataract extraction; therefore, additional medical necessity justification by the treating physician beyond inclusion on the order is not necessary.

Tinted lenses used as sunglasses which are provided to an aphakic patient in addition to regular prosthetic lenses will be denied as not medically necessary. Tinted lenses used as sunglasses which are prescribed to a pseudophakic patient in addition to regular prosthetic lenses will be denied as non-covered.

For patients who are aphakic who do not have an IOL (ICD-9 379.31, 743.35), the following lenses or combinations of lenses are covered when determined to be medically necessary:
1) bifocal lenses in frames; or
2) lenses in frames for far vision and lenses in frames for near vision; or
3) when a contact lens(es) for far vision is prescribed (including cases of binocular and monocular aphakia), payment will be made for the contact lens(es), and lens(es) in frames for near vision to be worn at the same time as the contact lens(es), and lenses in frames to be worn when the contacts have been removed.

Refractive lenses are covered even though the surgical removal of the natural lens occurred before Medicare entitlement.

Scratch resistant coating (V2760) and transition/progressive lenses (V2781) are non-covered as a deluxe item.

Only standard frames (V2020) are covered. Additional charges for deluxe frames (V2025) are non-covered.

When hydrophilic soft contact lenses (V2520–V2523) are used as a corneal dressing, they are denied as non-covered because in this situation they do not meet the definition of a prosthetic device. However, if these lenses are used for refraction and meet the coverage criteria described above, they are covered.

Contact lens cleaning solution and normal saline for contact lenses are non-covered.

Low vision aids (V2600-V2615) are non-covered items because coverage under the Medicare prosthetic benefit is limited to congenital absence or surgical removal of the lens of the eye.

CODING GUIDELINES:

The RT and LT modifiers must be used with all HCPCS codes in this policy except codes V2020, V2025 and V2600. When lenses are provided bilaterally and the same code is used for both lenses, bill both on the same claim line using the LTRT modifier and 2 units of service.

Codes V2100 - V2218, V2299 - V2318, V2399 - V2499, V2700, and V2770 describe specific eyeglasses lenses. Only one of these codes may be billed for each lens provided.

Codes V2219, V2220, V2319, V2320, V2710 - V2760, and V2781, describe add-on features of lenses. They are billed in addition to codes for the basic lens.

Code V2744 is used for any type of photochromatic lens, either glass or plastic.

When billing claims for deluxe frames, use code V2020 for the cost of standard frames and a second line item using code V2025 for the difference between the charges for the deluxe frames and the standard frames.

When billing claims for progressive lens, use the appropriate code for the standard bifocal (V2200 - V2299) or trifocal (V2300 - V2399) lens and a second line item using code V2781 for the difference between the charge for the progressive lens and the standard lens.

Suppliers should refer to the Statistical Analysis DME Regional Carrier (SADMERC) web site or contact the SADMERC for guidance on the correct coding for these items.

DOCUMENTATION:

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the lens(es) which is signed and dated by the treating physician must be kept on file by the supplier. The order must include the ICD-9 diagnosis code, and/or a narrative diagnosis for the condition necessitating the lens(es). (If the ordering physician is also the supplier, the prescription is an integral part of the patient's record.)

All claims must include the ICD-9 diagnosis code relating to the need for the item.

If aphakia is the result of the removal of a previously implanted lens, the date of the surgical removal of the lens must accompany the claim.

For tints (V2740 - V2744), anti-reflective coating (V2750), or oversized lenses (V2780), if they are specifically ordered by the treating physician and are not only a patient preference item, the KX modifier should be added to the code. The KX modifier may only be used when this requirement is met. When the KX modifier is billed, documentation to support the medical necessity of the lens feature must be available to the DMERC on request.

Refer to the *Supplier Manual* for more information on orders, medical records and supplier documentation.

EFFECTIVE DATE: Claims for dates of service on or after July 1, 2002.

This is a revision to a previously published policy.

NOTE: Claims received for eyeglasses or contact lenses (i.e., V codes) billed with Place of Service (POS) 11 for physician's office will be denied. Claims for eyeglasses or contact lenses should be resubmitted with the proper POS codes, which are 12 (Patient's Home), 31 (Skilled Nursing Facility),32 (Nursing Facility) or 33 (Custodial Care Facility).

NOTE: The DMERC policy on refractive lenses allows coverage for only one pair of contacts or one pair of frames and lenses for patients undergoing cataract extraction with the insertion of intraocular lenses (IOLs) [pseudophakia, ICD-9-CM V43.1]. In order to more accurately adjudicate claims, it will be necessary to document the date(s) of cataract surgery on a claim. ***In order to more accurately adjudicate claims for refractive lenses, it is necessary to document the date(s) of cataract surgery on the CMS-1500 (12-90) claim form. The surgery date must be entered in Item 19. Claims received without dates of cataract surgery included on the claim will be denied for lack of sufficient documentation. Suppliers filing EMC may enter the surgery date information in the HAØ record.***

In addition, it is sometimes necessary to remove an IOL because of complications, rendering the patient aphakic in the affected eye [ICD-9-CM 379.31]. However, Medicare files may indicate the patient is pseudophakic rather than aphakic, due to information furnished on prior claims. ***Claims for patients who have undergone IOL removal require documentation of the IOL removal to allow payment for subsequent refractive lenses.***

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V2313	Spherocylinder, trifocal, plus or minus 7.25D to plus or minus 12.00D sphere, 4.25 to 6.00D cylinder, per lens
V2314	Spherocylinder, trifocal, sphere over plus or minus 12 .00D, per lens
V2315	Lenticular, (myodisc), per lens, trifocal
V2316	Lenticular non-aspheric, per lens, trifocal
V2317	Lenticular, aspheric lens, trifocal
V2318	Aniseikonic lens, trifocal
V2319	Trifocal seg width over 28 mm
V2320	Trifocal add over 3.25D
V2399	Specialty trifocal (by report)
V2410	Variable asphericity lens, single vision, full field, glass or plastic, per lens
V2430	Variable asphericity lens, bifocal, full field, glass or plastic, per lens
V2499	Variable sphericity lens, other type

Contact Lenses

V2500	Contact lens, PMMA, spherical, per lens
V2501	Contact lens, PMMA, toric or prism ballast, per lens
V2502	Contact lens, PMMA, bifocal, per lens
V2503	Contact lens, PMMA, color vision deficiency, per lens
V2510	Contact lens, gas permeable, spherical, per lens
V2511	Contact lens, gas permeable, toric, prism ballast, per lens
V2512	Contact lens, gas permeable, bifocal, per lens
V2513	Contact lens, gas permeable, extended wear, per lens
V2520	Contact lens, hydrophilic, spherical, per lens
V2521	Contact lens, hydrophilic, toric, or prism ballast, per lens
V2522	Contact lens, hydrophilic, bifocal, per lens
V2523	Contact lens, hydrophilic, extended wear, per lens
V2530	Contact lens, scleral, gas impermeable, per lens
V2531	Contact lens, scleral, gas permeable, per lens
V2599	Contact lens, other type

Low Vision Aids

V2600	Hand held low vision aids and other non-spectacle mounted aids
V2610	Single lens spectacle mounted low vision aids
V2615	Telescopic and other compound lens system, including distance vision telescopic, near vision telescopes and compound microscopic lens system

Miscellaneous

V2700	Balance lens, per lens
V2710	Slab off prism, glass or plastic, per lens
V2715	Prism, per lens
V2718	Press-on lens, Fresnell prism, per lens

V2730	Special base curve, glass or plastic, per lens
V2740	Tint, plastic, rose 1 or 2 per lens
V2741	Tint, plastic, other than rose 1or 2, per lens
V2742	Tint, glass, rose 1 or 2, per lens
V2743	Tint, glass, other than rose 1 or 2, per lens
V2744	Tint, photochromatic, per lens
V2750	Anti-reflective coating, per lens
V2755	U-V lens, per lens
V2760	Scratch resistant coating, per lens
V2770	Occluder lens, per lens
V2780	Oversize lens, per lens
V2781	Progressive lens, per lens
V2799	Vision service, miscellaneous

HCPCS Modifier:

KX	Specific required documentation on file
LT	Left side
RT	Right side

BENEFIT CATEGORY: Prosthetic Device

DEFINITIONS:

Aphakia is the absence of the lens of the eye.

Pseudophakia is an eye in which the natural lens has been replaced with an artificial intra-ocular lens (IOL).

Photochromatic lenses are those in which the degree of tint changes in response to changes in ambient light.

Progressive lens (V2781) is a multifocal lens that gradually changes in lens power from the top to the bottom of the lens, eliminating the line(s) that would otherwise be seen in a bifocal or trifocal lens.

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.

Refractive lenses are covered when they are medically necessary to restore the vision normally provided by the natural lens of the eye of an individual lacking the organic lens because of surgical removal or congenital absence. Covered diagnoses are limited to pseudophakia (ICD-9 V43.1), aphakia (ICD-9 379.31), and congenital aphakia (ICD-9 743.35). Lenses provided for other diagnoses will be denied as non-covered.

After each cataract surgery with insertion of an intraocular lens (ICD-9 V43.1), coverage is limited to one pair of eyeglasses or contact lenses. Replacement frames, eyeglass lenses and contact lenses are

non-covered. If a beneficiary has a cataract extraction with IOL insertion in one eye, subsequently has a cataract extraction with IOL insertion in the other eye, and does not receive eyeglasses or contact lenses between the two surgical procedures, Medicare covers only one pair of eyeglasses or contact lenses after the second surgery. If a beneficiary has a pair of eyeglasses, has a cataract extraction with IOL insertion, and receives only new lenses but not new frames after the surgery, the benefit would not cover new frames at a later date (unless it follows subsequent cataract extraction in the other eye).

Tints (V2740 - V2744), anti-reflective coating (V2750), or oversize lenses (V2780) are covered only when they are medically necessary for the individual patient and the medical necessity is documented by the treating physician. When these features are provided as a patient preference item and are billed without a KX modifier (see Documentation section), they will be denied as not medically necessary.

U-V lenses (V2755) are considered reasonable and necessary following cataract extraction; therefore, additional medical necessity justification by the treating physician beyond inclusion on the order is not necessary.

Tinted lenses used as sunglasses which are provided to an aphakic patient in addition to regular prosthetic lenses will be denied as not medically necessary. Tinted lenses used as sunglasses which are prescribed to a pseudophakic patient in addition to regular prosthetic lenses will be denied as non-covered.

For patients who are aphakic who do not have an IOL (ICD-9 379.31, 743.35), the following lenses or combinations of lenses are covered when determined to be medically necessary:

1) bifocal lenses in frames; or
2) lenses in frames for far vision and lenses in frames for near vision; or
3) when a contact lens(es) for far vision is prescribed (including cases of binocular and monocular aphakia), payment will be made for the contact lens(es), and lens(es) in frames for near vision to be worn at the same time as the contact lens(es), and lenses in frames to be worn when the contacts have been removed.

Refractive lenses are covered even though the surgical removal of the natural lens occurred before Medicare entitlement.

Scratch resistant coating (V2760) and transition/progressive lenses (V2781) are non-covered as a deluxe item.

Only standard frames (V2020) are covered. Additional charges for deluxe frames (V2025) are non-covered.

When hydrophilic soft contact lenses (V2520–V2523) are used as a corneal dressing, they are denied as non-covered because in this situation they do not meet the definition of a prosthetic device. However, if these lenses are used for refraction and meet the coverage criteria described above, they are covered.

Contact lens cleaning solution and normal saline for contact lenses are non-covered.

Low vision aids (V2600-V2615) are non-covered items because coverage under the Medicare prosthetic benefit is limited to congenital absence or surgical removal of the lens of the eye.

CODING GUIDELINES:

The RT and LT modifiers must be used with all HCPCS codes in this policy except codes V2020, V2025 and V2600. When lenses are provided bilaterally and the same code is used for both lenses, bill both on the same claim line using the LTRT modifier and 2 units of service.

Codes V2100 - V2218, V2299 - V2318, V2399 - V2499, V2700, and V2770 describe specific eyeglasses lenses. Only one of these codes may be billed for each lens provided.

Codes V2219, V2220, V2319, V2320, V2710 - V2760, and V2781, describe add-on features of lenses. They are billed in addition to codes for the basic lens.

Code V2744 is used for any type of photochromatic lens, either glass or plastic.

When billing claims for deluxe frames, use code V2020 for the cost of standard frames and a second line item using code V2025 for the difference between the charges for the deluxe frames and the standard frames.

When billing claims for progressive lens, use the appropriate code for the standard bifocal (V2200 - V2299) or trifocal (V2300 - V2399) lens and a second line item using code V2781 for the difference between the charge for the progressive lens and the standard lens.

Suppliers should refer to the Statistical Analysis DME Regional Carrier (SADMERC) web site or contact the SADMERC for guidance on the correct coding for these items.

DOCUMENTATION:

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the lens(es) which is signed and dated by the treating physician must be kept on file by the supplier. The order must include the ICD-9 diagnosis code, and/or a narrative diagnosis for the condition necessitating the lens(es). (If the ordering physician is also the supplier, the prescription is an integral part of the patient's record.)

All claims must include the ICD 9 diagnosis code relating to the need for the item.

If aphakia is the result of the removal of a previously implanted lens, the date of the surgical removal of the lens must accompany the claim.

For tints (V2740 - V2744), anti-reflective coating (V2750), or oversized lenses (V2780), if they are specifically ordered by the treating physician and are not only a patient preference item, the KX modifier should be added to the code. The KX modifier may only be used when this requirement is met. When the KX modifier is billed, documentation to support the medical necessity of the lens feature must be available to the DMERC on request.

Refer to the *Supplier Manual* for more information on orders, medical records and supplier documentation.

EFFECTIVE DATE: Claims for dates of service on or after July 1, 2002.

This is a revision to a previously published policy.

NOTE: Claims received for eyeglasses or contact lenses (i.e., V codes) billed with Place of Service (POS) 11 for physician's office will be denied. Claims for eyeglasses or contact lenses should be resubmitted with the proper POS codes, which are 12 (Patient's Home), 31 (Skilled Nursing Facility),32 (Nursing Facility) or 33 (Custodial Care Facility).

NOTE: The DMERC policy on refractive lenses allows coverage for only one pair of contacts or one pair of frames and lenses for patients undergoing cataract extraction with the insertion of intraocular lenses (IOLs) [pseudophakia, ICD-9-CM V43.1]. In order to more accurately adjudicate claims, it will be necessary to document the date(s) of cataract surgery on a claim. ***In order to more accurately adjudicate claims for refractive lenses, it is necessary to document the date(s) of cataract surgery on the CMS-1500 (12-90) claim form. The surgery date must be entered in Item 19. Claims received without dates of cataract surgery included on the claim will be denied for lack of sufficient documentation. Suppliers filing EMC may enter the surgery date information in the HAØ record.***

In addition, it is sometimes necessary to remove an IOL because of complications, rendering the patient aphakic in the affected eye [ICD-9-CM 379.31]. However, Medicare files may indicate the patient is pseudophakic rather than aphakic, due to information furnished on prior claims. ***Claims for patients who have undergone IOL removal require documentation of the IOL removal to allow payment for subsequent refractive lenses.***

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Chapter 51 - External Breast Prostheses

View Attachments

Chapter 51 contains the medical policy for external breast prostheses. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: External Breast Prostheses

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

A4280 Adhesive skin support attachment for use with external breast prosthesis, each
L8000 Breast prosthesis, mastectomy bra
L8001 Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, unilateral
L8002 Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, bilateral
L8010 Breast prosthesis, mastectomy sleeve
L8015 External breast prosthesis garment, with mastectomy form, post mastectomy
L8020 Breast prosthesis, mastectomy form
L8030 Breast prosthesis, silicone or equal
L8035 Custom breast prosthesis, post mastectomy, molded to patient model
L8039 Breast prosthesis, not otherwise classified

BENEFIT CATEGORY: Prosthetic Device

DEFINITIONS:

Code L8015 describes a camisole type undergarment with polyester fill

used post mastectomy.

A custom fabricated prosthesis is one which is individually made for a specific patient starting with basic materials. Code L8035 describes a molded-to-patient-model custom breast prosthesis. It is a particular type of custom fabricated prosthesis in which an impression is made of the chest wall and this impression is then used to make a positive model of the chest wall. The prosthesis is then molded on this positive model.

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, "reasonable and necessary" are defined by the following coverage and payment rules.

A breast prosthesis is covered for a patient who has had a mastectomy, ICD-9-CM diagnosis codes V45.71, 174.0-174.9.

An external breast prosthesis garment, with mastectomy form (L8015) is covered for use in the postoperative period prior to a permanent breast prosthesis or as an alternative to a mastectomy bra and breast prosthesis.

The additional features of a custom fabricated prosthesis (L8035) compared to a prefabricated silicone breast prosthesis, are not medically necessary. Therefore if an L8035 breast prosthesis is provided to a patient who has had a mastectomy, payment will be based on the allowance for the least costly medically appropriate alternative, L8030.

A mastectomy sleeve (L8010) is denied as noncovered, since it does not meet the definition of a prosthesis.

The useful lifetime expectancy for silicone breast prostheses is 2 years. For fabric, foam, or fiber filled breast prostheses, the useful lifetime expectancy is 6 months. Replacement sooner than the useful lifetime because of ordinary wear and tear will be denied as noncovered.
An external breast prosthesis of the same type can be replaced at any time if it is lost or is irreparably damaged (this does not include ordinary wear and tear). An external breast prosthesis of a different type can be covered at any time if there is a change in the patient's medical condition necessitating a different type of item.

CODING GUIDELINES:

Code K0400 (Adhesive skin support attachment for use with external breast prosthesis, each) is invalid for claim submission to the DMERC as of the effective date of this policy revision. It has been replaced by code A4280.

Code A4280 should be used when billing for an adhesive skin support that attaches an external breast prosthesis directly to the chest wall.

The right (RT) and left (LT) modifiers must be used with these codes. When the same code for two breast prostheses are billed for both breasts on the same date, the items (RT and LT) must be entered on the same line of the claim form using the RTLT modifier and two units of service.

DOCUMENTATION:

For an item to be considered for coverage and payment by Medicare, the information submitted by the supplier must be corroborated by documentation in the patient's medical records that Medicare coverage criteria have been met. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals, or test reports. This documentation must be available to the DMERC upon request.

An order for the breast prosthesis, which shows the type of prosthesis, and which is signed and dated by the treating physician, must be kept on file by the supplier. A narrative diagnosis and/or ICD-9-CM diagnosis code which describes the condition which necessitates the breast prosthesis must be present on each order for a breast prosthesis or related item.

The ICD –9-CM diagnosis code must be included on each claim for the prosthesis or related item.

If the patient's medical condition changes, this should be documented by the patient's physician submitting a new order which explains the need for a different type of breast prosthesis. The order must be kept in the supplier's files but need not be submitted with the claim.

Refer to the Supplier Manual for more information about orders, medical records and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after April 1, 2002.

NOTE: The first paragraph under Coding Guidelines (above) is incorrect. HCPCS code A4280 already had replaced HCPCS code K0400 for dates of service on or after January 2000. Code K0400 has been invalid for submission to the DMERC since April 1, 2000.

This is a revision of a previously published policy.

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Chapter 52 - Urological Supplies

View Attachments

Chapter 52 contains the medical policy for urological supplies. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Urological Supplies

HCPCS CODES

The appearance of a code in this section does not necessarily indicate coverage.

A4310	Insertion tray without drainage bag and without catheter (accessories only)
A4311	Insertion tray without drainage bag with indwelling catheter, Foley type, two-way latex with coating (teflon, silicone, silicone elastomer or hydrophilic, etc.)
A4312	Insertion tray without drainage bag with indwelling catheter, Foley type, two-way, all silicone
A4313	Insertion tray without drainage bag with indwelling catheter, Foley type, three-way, for continuous irrigation
A4314	Insertion tray with drainage bag with indwelling catheter, Foley type, two-way latex with coating (teflon, silicone, silicone elastomer or hydrophilic, etc.)
A4315	Insertion tray with drainage bag with indwelling catheter, Foley type, two-way, all silicone
A4316	Insertion tray with drainage bag with indwelling catheter, Foley type, three-way, for continuous irrigation
A4319	Sterile water irrigation solution, 1000 ml

A4320	Irrigation tray with bulb or piston syringe, any purpose
A4321	Therapeutic agent for urinary catheter irrigation
A4322	Irrigation syringe, bulb or piston, each
A4323	Sterile saline irrigation solution, 1000 ml
A4324	Male external catheter, with adhesive coating, each
A4325	Male external catheter, with adhesive strip, each
A4326	Male external catheter specialty type, e.g., inflatable, faceplate, etc. each
A4327	Female external urinary collection device, meatal cup, each
A4328	Female external urinary collection device, pouch, each
A4331	Extension drainage tubing, any type, any length, with connector/adaptor, for use with urinary leg bag or urostomy pouch, each
A4332	Lubricant, individual sterile packet, for insertion of urinary catheter, each
A4333	Urinary catheter anchoring device, adhesive skin attachment, each
A4334	Urinary catheter anchoring device, leg strap, each
A4335	Incontinence supply, miscellaneous
A4338	Indwelling catheter, Foley type, two-way latex with coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each
A4340	Indwelling catheter, specialty type, (e.g., Coude, mushroom, wing, etc.), each
A4344	Indwelling catheter, Foley type, two-way, all silicone, each
A4346	Indwelling catheter, Foley type, three-way for continuous irrigation, each
A4347	Male external catheter with or without adhesive, with or without anti-reflux device; per dozen
A4348	Male external catheter with integral collection compartment, extended wear, each (e.g., 2 per month)
A4351	Intermittent urinary catheter, straight tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each
A4352	Intermittent urinary catheter, Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each
A4353	Intermittent urinary catheter, with insertion supplies
A4354	Insertion tray with drainage bag but without catheter
A4355	Irrigation tubing set for continuous bladder irrigation through a three-way indwelling Foley catheter, each
A4356	External urethral clamp or compression device (not to be used for catheter clamp), each

A4357	Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each
A4358	Urinary drainage bag, leg or abdomen, vinyl, with or without tube, with straps, each
A4359	Urinary suspensory without leg bag, each
A4360	Adult incontinence garment (e.g., brief, diaper), each
A4365	Adhesive remover wipes, any type, per 50
A4402	Lubricant, per ounce
A4455	Adhesive remover or solvent (for tape, cement or other adhesive), per ounce
A4554	Disposable underpads, all sizes, (e.g., Chux's)
A5102	Bedside drainage bottle with or without tubing, rigid or expandable, each
A5105	Urinary suspensory; with leg bag, with or without tube
A5112	Urinary leg bag, latex
A5113	Leg strap, latex, replacement only, per set
A5114	Leg strap, foam or fabric, replacement only, per set
A5131	Appliance cleaner, incontinence and ostomy appliances, per 16 oz.
A5200	Percutaneous catheter/tube anchoring device, adhesive skin attachment
A9270	Non-covered item or service
K0572	Tape, non-waterproof, per 18 square inches
K0573	Tape, waterproof, per 18 square inches

HCPCS MODIFIERS

KX	Specific required documentation on file
GY	Item or service statutorily excluded or does not meet the definition of any Medicare benefit

BENEFIT CATEGORY: Prosthetic Devices

DEFINITIONS

A meatal cup female external urinary collection device (A4327) is a plastic cup which is held in place around the female urethra by suction or pressure and is connected to a urinary drainage container such as a bag or bottle.

A pouch type female external collection device (A4328) is a plastic pouch which is attached to the periurethral area with adhesive and which can be connected to a urinary drainage container such as a bag or bottle.

The general term "external urinary collection devices" used in this policy includes male external catheters and female pouches or meatal cups. This term does not include diapers or other types of absorptive pads.

Sterile catheterization technique involves the use of a new, sterile packaged catheter and sterile lubricant for each catheterization. It may also involve use of sterile gloves and drape and use of an antiseptic solution to cleanse the periurethral area. Clean, non-sterile intermittent catheterization technique involves the use of soap and water for cleansing of the periurethral area, a reusable catheter which is cleansed between episodes, and non-sterile lubricant.

A urinary catheter anchoring device described by code A4333 has an adhesive surface which attaches to the patient's skin and a mechanism for releasing and re-anchoring the catheter multiple times without changing the anchoring device.

A urinary catheter anchoring device described by code A4334 is a strap which goes around a patient's leg and has a mechanism for releasing and re-anchoring the catheter multiple times without changing the anchoring device.

A urinary intermittent catheter with insertion supplies (A4353) is a kit which includes a catheter, lubricant, gloves, antiseptic solution, applicators, drape, and a tray or bag in a sterile package intended for single use.

Therapeutic agent for urinary irrigation (A4321) is defined as a solution containing agents in addition to saline or sterile water (for example acetic acid or hydrogen peroxide) which is used for the treatment or prevention of urinary catheter obstruction.

COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must (1) be eligible for a defined Medicare Benefit Category, (2) be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member, and (3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this regional medical review policy, "reasonable and necessary" is defined by the following coverage and payment rules.

General

Urinary catheters and external urinary collection devices are covered to drain or collect urine for a patient who has permanent urinary incontinence or permanent urinary retention. Permanent urinary retention is defined as retention that is not expected to be medically or surgically corrected in that patient within 3 months.

If the catheter or the external urinary collection device meets the coverage criteria then the related supplies that are necessary for their effective use are

also covered. Urological supplies that are not used with, or for which use is not related to the covered use of catheters or external urinary collection devices (i.e., drainage and/or collection of urine from the bladder) will be denied as non-covered. Urological supplies billed without a KX modifier (see Documentation section) will be denied as non-covered.

The patient must have a permanent impairment of urination. This does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the medical record, including the judgement of the attending physician, indicates the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Catheters and related supplies will be denied as non-covered in situations in which it is expected that the condition will be temporary.

When urological supplies are furnished in a physician's office, they may be billed to the DMERC only if the patient's condition meets the definition of permanence. (In this situation, the catheters and related supplies are covered under the prosthetic device benefit.) If the patient's condition is expected to be temporary, urological supplies may not be billed to the DMERC. (In this situation, they are considered as supplies provided incident to a physician's service and payment is included in the allowance for the physician services which are processed by the local carrier.) When billing for urological supplies furnished in a physician's office for a permanent impairment, use the place of service code corresponding to the beneficiary's current place of residence; do not use POS 11, office.

The use of a urological supply for the treatment of chronic urinary tract infection or other bladder condition in the absence of permanent urinary incontinence or retention is non-covered. Since the patient's urinary system is functioning, the criteria for coverage under the prosthetic benefit provision are not met.

The medical necessity for use of a greater quantity of supplies than the amounts specified in the policy must be well documented in the patient's medical record and may be requested by the DMERC.

Indwelling Catheters (A4311 - A4316, A4338 - A4346)
No more than one catheter per month is covered for routine catheter maintenance. Non-routine catheter changes are covered when documentation substantiates medical necessity, such as for the following indications:

1. Catheter is accidentally removed (e.g., pulled out by patient)

2. Malfunction of catheter (e.g., balloon does not stay inflated, hole in catheter)

3. Catheter is obstructed by encrustation, mucous plug, or blood clot

4. History of recurrent obstruction or urinary tract infection for which it has been established that an acute event is prevented by a scheduled change frequency of more than once per month

When a specialty indwelling catheter (A4340) or an all silicone catheter (A4344, A4312, or A4315) is used, there must be documentation in the patient's medical record of the medical necessity for that catheter rather than a straight Foley type catheter with coating (such as recurrent encrustation, inability to pass a straight catheter, or sensitivity to latex). In addition, the particular catheter must be necessary for the patient. For example, use of a Coude (curved) tip indwelling catheter (A4340) in female patients is rarely medically necessary. Documentation of medical necessity may be requested by the DMERC. If documentation is requested and does not substantiate medical necessity, payment will be made based on the least costly medically appropriate alternative -- A4338, A4311, or A4314 respectively.

A three-way indwelling catheter either alone (A4346) or with other components (A4313 or A4316) will be covered only if continuous catheter irrigation is medically necessary. (Refer to the section "Continuous Irrigation of Indwelling Catheters" for indications for continuous catheter irrigations.) In other situations, payment will be based on the least costly medically appropriate alternative (A4338, A4311, or A4314 respectively).

Catheter Insertion Tray (A4310-A4316, A4353, A4354)
One insertion tray will be covered per episode of indwelling catheter insertion. More than one tray per episode will be denied as not medically necessary.

One intermittent catheter with insertion supplies (A4353) will be covered per episode of medically necessary sterile intermittent catheterization (see below). Catheter insertion trays will be denied as not medically necessary for clean, non-sterile intermittent catheterization.

Insertion trays that contain component parts of the urinary collection system, (e.g., drainage bags and tubing) are inclusive sets and payment for additional component parts will be allowed only per the stated criteria in each section of the policy.

Urinary Drainage Collection System (A4314-A4316, A4354, A4357, A4358, A5102, A5112)
Payment will be made for routine changes of the urinary drainage collection system as noted below. Additional charges will be allowed for medically necessary non-routine changes when the documentation substantiates the medical necessity, (e.g., obstruction, sludging, clotting of blood, or chronic, recurrent urinary tract infection).

Usual Maximum Quantity of Supplies

Code	#/mo.	#/3 mo.
A4314	1	-
A4315	1	-
A4316	1	-
A4354	1	-
A4357	2	-
A4358	2	-
A5102	-	1
A5112	1	-

Leg bags are indicated for patients who are ambulatory or are chair or wheelchair bound. The use of leg bags for bedridden patients would be denied as not medically necessary.

If there is a catheter change (A4314-A4316, A4354) and an additional drainage bag (A4357) change within a month, the combined utilization for A4314-A4316, A4354 and A4357 should be considered when determining if additional documentation should be submitted with the claim. For example, if 1 unit of A4314 and 1 unit of A4357 are provided, this should be considered as two drainage bags, which is the usual maximum quantity of drainage bags needed for routine changes.

Payment will be made for either a vinyl leg bag (A4358) or a latex leg bag (A5112). The use of both is not medically necessary.

The medical necessity for drainage bags containing gel matrix or other material which are intended to be disposed of on a daily basis has not been established. Payment for this type of bag will be based on the allowance and usual frequency of change for the least costly medically appropriate alternative, code A4357.

Intermittent Irrigation of Indwelling Catheter

Supplies for the intermittent irrigation of an indwelling catheter are covered when they are used on an as needed (non-routine) basis in the presence of acute obstruction of the catheter. Routine intermittent irrigations of a catheter will be denied as not medically necessary. Routine irrigations are defined as those performed at predetermined intervals. In individual cases, the DMERC may request a copy of the order for irrigation and documentation in the patient's medical record of the presence of acute catheter obstruction when irrigation supplies are billed.

Covered supplies for medically necessary non-routine irrigation of a catheter include either an irrigation tray (A4320) or an irrigation syringe (A4322), and sterile saline (A4323) or sterile water (A4319). When syringes, trays, sterile saline or water are used for routine irrigation, they will be denied as not medically necessary. Irrigation solutions containing antibiotics and chemotherapeutic agents (A9270) will be denied as non-

covered. Irrigating solutions such as acetic acid or hydrogen peroxide which are used for the treatment or prevention of urinary obstruction (A4321) will be denied as not medically necessary.

Irrigation supplies that are used for care of the skin or perineum of incontinent patients are non-covered.

Continuous Irrigation of Indwelling Catheter
Supplies for continuous irrigation of a catheter are covered if there is a history of obstruction of the catheter and the patency of the catheter cannot be maintained by intermittent irrigation in conjunction with medically necessary catheter changes. Continuous irrigation as a primary preventative measure (i.e., no history of obstruction) will be denied as not medically necessary. Documentation must substantiate the medical necessity of catheter irrigation and in particular continuous irrigation as opposed to intermittent irrigation. The records must also indicate the rate of solution administration and the duration of need. This documentation may be requested by the DMERC.

Covered supplies for medically necessary continuous bladder irrigation include a three-way Foley catheter (A4313, A4316, A4346), irrigation tubing set (A4355), and sterile saline (A4323) or sterile water (A4319). More than one irrigation tubing set per day for continuous catheter irrigation will be denied as not medically necessary.

Irrigation solutions containing antibiotics and chemotherapeutic agents (A9270) will be denied as non-covered. Payment for irrigating solutions such as acetic acid or hydrogen peroxide will be based on the allowance for sterile water (A4319) or sterile saline (A4323).

Continuous irrigation is a temporary measure. Continuous irrigation for more than 2 weeks is rarely medically necessary. The patient's medical records should indicate this medical necessity and these medical records may be requested by the DMERC.

Intermittent Catheterization
Intermittent catheterization is covered when basic coverage criteria are met and the patient or caregiver can perform the procedure. When clean, non-sterile catheterization technique is used, Medicare will cover replacement of intermittent catheters (A4351-A4352) on a weekly basis unless there is documentation of the medical necessity for more frequent replacement. Non-sterile lubricating gel (A4402) would be covered for use with clean, non-sterile catheterization technique. Eight units of service (8 oz.) would be covered per month. An individual packet of lubricant (A4332) is not medically necessary for clean, non-sterile intermittent catheterization.

Intermittent catheterization using sterile technique is covered when the patient requires catheterization and the patient meets one of the following criteria (1-5):

1. The patient resides in a nursing facility,

2. The patient is immunosuppressed, for example (not all inclusive):
   - on a regimen of immunosuppressive drugs post-transplant,
   - on cancer chemotherapy,
   - has AIDS,
   - has a drug-induced state such as chronic oral corticosteroid use

3. The patient has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization,

4. The patient is a spinal-cord injured female with neurogenic bladder who is pregnant (for duration of pregnancy only),

5. The patient has had distinct, recurrent urinary tract infections, while on a program of clean intermittent catheterization, twice within the 12-month prior to the initiation of sterile intermittent catheterization.

A patient would be considered to have a urinary tract infection if they have a urine culture with greater than 10,000 colony forming units of a urinary pathogen AND concurrent presence of one or more of the following signs, symptoms or laboratory findings:

- Fever (oral temperature >38° C [100.4° F])
- Systemic leukocytosis
- Change in urinary urgency, frequency, or incontinence
- Appearance of new or increase in autonomic dysreflexia (sweating, bradycardia, blood pressure elevation)
- Physical signs of prostatitis, epididymitis, orchitis
- Increased muscle spasms
- Pyuria (greater than 5 white blood cells [wbc's] per high-powered field)

The medical necessity for use of sterile intermittent catheterization for reasons other than the criteria (1-5) listed above may be presented for individual consideration.

For each episode of covered sterile catheterization, Medicare will cover a) one catheter (A4351, A4352) and an individual packet of lubricant (A4332) or b) an intermittent catheter kit (A4353) - see Definition section for contents of the kit. The kit code should be used for billing even if the components are packaged separately rather than together as a kit. If sterile catheterization is not medically necessary, sterile supplies will be denied as not medically necessary.

Use of a Coude (curved) tip catheter (A4352) in female patients is rarely medically necessary. When a Coude tip catheter is used (either male or female patients), there must be documentation in the patient's medical record of the medical necessity for that catheter rather than a straight tip catheter (A4351). An example would be the inability to catheterize with a straight tip catheter. This documentation may be requested by the DMERC. If documentation is requested and does not substantiate medical necessity, payment will be based on the least costly medically appropriate alternative (A4351).

External Catheters/Urinary Collection Devices
Male external catheters (condom-type) or female external urinary collection devices are covered for patients who have permanent urinary incontinence when used as an alternative to an indwelling catheter.

The utilization of male external catheters (A4324 or A4325) generally should not exceed 35 per month. Greater utilization of these devices must be accompanied by documentation of medical necessity.

Adhesive strips or tape used with code A4325 (Male external catheter, with adhesive strip, each) are included in the allowance for that code and are not separately payable by the DMERC. If adhesive strips or tape are used with code A4325 (Male external catheter, with adhesive coating, each), payment will be denied as not medically necessary.

Male external catheters (condom-type) or female external urinary collection devices will be denied as not medically necessary when ordered for patients who also use an indwelling catheter.

Specialty type male external catheters such as those that inflate or that include a faceplate (A4326) are covered only when documentation substantiates the medical necessity for such a catheter. Payment will be based on the least costly medically appropriate alternative if documentation does not substantiate medical necessity.

For female external urinary collection devices, more than one meatal cup (A4327) per week or more than one pouch (A4328) per day will be denied as not medically necessary.

Miscellaneous Supplies
Appliance cleaner (A5131) is covered when used to clean the inside of certain urinary collecting appliances (A5102, A5112). More than one unit of service (16 oz.) per month is rarely medically necessary.

One external urethral clamp or compression device (A4356) is covered every 3 months or sooner if the rubber/foam casing deteriorates.

Tape (K0572, K0573) which is used to secure an indwelling catheter to the patient's body is covered. More than 10 units (1 unit = 18 sq.in.; 10 units = 180 sq.in. = 5 yds. of 1 inch tape) per month will be denied as not medically

necessary unless the claim is accompanied by documentation justifying a larger quantity in the individual case.

Adhesive catheter anchoring devices (A4333) and catheter leg straps (A4334) for indwelling urethral catheters are covered. More than 3 per week of A4333 or 1 per month of A4334 will be denied as not medically necessary unless the claim is accompanied by documentation justifying a larger quantity in the individual case. A catheter/tube anchoring device (A5200) is covered and separately payable when it is used to anchor a covered suprapubic tube or nephrostomy tube. If code A5200 is used to anchor an indwelling urethral catheter, payment will be based on the allowance for the least costly medically appropriate alternative, A4333.

Extension tubing (A4331) will be covered for use with a latex urinary leg bag (A5112). It is included in the allowance for codes A4314, A4315, A4316, A4354, A4357, A4358 and A5105 and should not be separately billed with these codes.

Other supplies used in the management of incontinence, including but not limited to the following items, will be denied as non-covered because they are not prosthetic devices nor are they required for the effective use of a prosthetic device:

1. Creams, salves, lotions, barriers (liquid, spray, wipes, powder, paste) or other skin care products (A6250)
2. Catheter care kits (A9270)
3. Adhesive remover (A4455, A4365) (Coverage remains for use with ostomy supplies.)
4. Catheter clamp or plug (A9270)
5. Disposable underpads, e.g. Chux (A4554)
6. Diapers, or incontinent garments, disposable or reusable (A4360)
7. Drainage bag holder or stand (A9270)
8. Urinary suspensory without leg bag (A4359)
9. Measuring container (A9270)
10. Urinary drainage tray (A9270)
11. Gauze pads (A6216-A6218) and other dressings (Coverage remains under other benefits, e.g., surgical dressings.)
12. Other incontinence products not directly related to the use of a covered urinary catheter or external urinary collection device (A9270)

CODING GUIDELINES

Procedure code A4347 is not valid for claims submitted to the DMERC. When billing for male external catheters, use code A4324 or A4325 and one unit of service for each catheter supplied.

Irrigation solutions containing antibiotics and chemotherapeutic agents

should be coded A9270. Irrigating solutions such as acetic acid or hydrogen peroxide which are used for the treatment or prevention of urinary obstruction should be coded A4321.

Adhesive strips or tape used with code A4325 (Male external catheter, with adhesive strip, each) should not be billed separately. Adhesive strips and tape used in conjunction with code A4324 (Male external catheter, with adhesive coating, each) should be billed with code A4335.

Adhesive catheter anchoring devices that are used with indwelling urethral catheters are billed using codes A4333 and A43343, respectively. An anchoring device used with a percutaneous catheter/tube (e.g., suprapubic tube, nephrostomy tube) is billed using code A5200.

Replacement leg straps (A5113, A5114) are used with a urinary leg bag (A4358, A5105, or A5112). These codes are not used for a leg strap for an indwelling catheter.

Code A6265 (Tape, all types, per 18 square inches) is not valid for claim submission to the DMERC. Codes K0572 and K0573 should be used instead.

An external catheter that contains a barrier for attachment should be coded using A4335.

Codes for ostomy barriers (A5119, A4369-A4371) should not be used for skin care products used in the management of urinary incontinence.

In the following table, the Column I code includes the items identified by the codes in column II. The Column I code must be used instead of multiple Column II codes when the items are provided at the same time.

Column I	**Column II**
A4310	A4332
A4311	A4310, A4338, A4332
A4312	A4310, A4344, A4332
A4313	A4310, A4346, A4332
A4314	A4310, A4311, A4338, A4354, A4357, A4331, A4332
A4315	A4310, A4312, A4344, A4354, A4357, A4331, A4332
A4316	A4310, A4313, A4346, A4354, A4357, A4331, A4332
A4325	K0572, K0573
A4353	A4310, A4351, A4352, A4332
A4354	A4310, A4357, A4331, A4332

A4357	A4331
A4358	A5113, A5114, A4331
A5112	A5113, A5114
A5105	A4358, A4359, A5112, A5113, A5114, A4331

If a code exists that includes multiple products, that code should be used in lieu of the individual codes.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) with any questions on the correct coding of these devices.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the supplies which has been signed and dated by the treating physician must be kept on file by the supplier. The order must include the type of supplies ordered and the approximate quantity to be used per unit of time. On the order, there must be a statement indicating whether the patient has permanent or temporary urinary incontinence or retention or other indication for use of a catheter or urinary collection device. If the order indicates permanent urinary incontinence or urinary retention, and if the item is a catheter, an external urinary collection device or a supply used with one of these items, the KX modifier should be added to the code for each urological supply on each claim submitted. The KX modifier may only be used when these requirements are met. If the requirements for the modifier are not met, the supplier can submit additional information with the claim to justify coverage.

If a supplier is billing for items which are non-covered, this must be indicated on the claim. The recommended way of doing this is to add the GY modifier to the code.

When billing for quantities of supplies greater than those described in the policy as the usual replacement frequency (e.g., more than one indwelling catheter per month, more than two bedside drainage bags per month, more than 35 male external catheters per month, etc.), the claim must include documentation supporting the medical necessity for the higher utilization. This information should be attached to a hard copy claim or entered in the HA0 record of an electronic claim.

The initial claim for catheters or kits used for sterile intermittent catheterization in the home must be accompanied by documentation supporting the medical necessity for sterile technique.

Refer to the Supplier Manual for additional information on orders, medical records and supplier documentation.

EFFECTIVE DATE: Claims for dates of service on or after July 1, 2002.

This is a revision of a previously published policy.

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Chapter 53 - Ankle-Foot/Knee-Ankle-Foot Orthotics

View Attachments

Chapter 53 contains the medical policy for ankle-foot and knee-ankle-foot orthotics. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Ankle-Foot/Knee-Ankle-Foot Orthotics

HCPCS CODES

L1900	Ankle foot orthosis, spring wire, dorsiflexion assist calf band, custom-fabricated
L1902	Ankle foot orthosis, ankle gauntlet, prefabricated, includes fitting and adjustment
L1904	Ankle foot orthosis, molded ankle gauntlet, custom-fabricated
L1906	Ankle foot orthosis, multiligamentus ankle support, prefabricated, includes fitting and adjustment
L1910	Ankle foot orthosis, posterior, single bar, clasp attachment to shoe counter, prefabricated, includes fitting and adjustment
L1920	Ankle foot orthosis, single upright with static or adjustable stop (Phelps or Perlstein type), custom-fabricated
L1930	Ankle foot orthosis, plastic or other material, prefabricated, includes fitting and adjustment
L1940	Ankle foot orthosis, plastic or other material, custom-fabricated
L1945	Ankle foot orthosis, plastic, rigid anterior tibial section (floor reaction), custom-fabricated
L1950	Ankle foot orthosis, spiral, (IRM type), plastic, custom-fabricated
L1960	Ankle foot orthosis, posterior solid ankle, plastic, custom-fabricated

L1970	Ankle foot orthosis, plastic with ankle joint, custom-fabricated
L1980	Ankle foot orthosis, single upright free plantar dorsiflexion, solid stirrup, calf band/cuff (single bar "BK" orthosis), custom-fabricated
L1990	Ankle foot orthosis, double upright free plantar dorsiflexion, solid stirrup, calf band/cuff (double bar "BK" orthosis), custom-fabricated
L2000	Knee-ankle-foot orthosis, single upright, free knee, free ankle, solid stirrup, thigh and calf bands/cuffs (single bar "AK" orthosis), custom-fabricated
L2010	Knee-ankle-foot orthosis, single upright, free ankle, solid stirrup, thigh and calf bands/cuffs (single bar "AK" orthosis), without knee joint, custom-fabricated
L2020	Knee-ankle-foot orthosis, double upright, free knee, free ankle, solid stirrup, thigh and calf bands/cuffs (double bar "AK" orthosis), custom-fabricated
L2030	Knee-ankle-foot orthosis, double upright, free ankle, solid stirrup, thigh and calf bands/cuffs, (double bar "AK" orthosis), without knee joint, custom-fabricated
L2035	Knee-ankle-foot orthosis, full plastic, static, (pediatric size) prefabricated, includes fitting and adjustment
L2036	Knee-ankle-foot orthosis, full plastic, double upright, free knee, custom-fabricated
L2037	Knee-ankle-foot orthosis, full plastic, single upright, free knee, custom-fabricated
L2038	Knee-ankle-foot orthosis, full plastic, without knee joint, multi-axis ankle, (Lively orthosis or equal), custom-fabricated
L2039	Knee-ankle-foot orthosis, full plastic, single upright, poly-axial hinge, medial lateral rotation control, custom-fabricated
L2106	Ankle foot orthosis, fracture orthosis, tibial fracture cast orthosis, thermoplastic type casting material, custom-fabricated
L2108	Ankle foot orthosis, fracture orthosis, tibial fracture cast orthosis, custom-fabricated
L2112	Ankle foot orthosis, fracture orthosis, tibial fracture orthosis, soft, prefabricated, includes fitting and adjustment
L2114	Ankle foot orthosis, fracture orthosis, tibial fracture orthosis, semi-rigid, prefabricated, includes fitting and adjustment
L2116	Ankle foot orthosis, fracture orthosis, tibial fracture orthosis, rigid, prefabricated, includes fitting and adjustment
L2126	Knee-ankle-foot orthosis, fracture orthosis, femoral fracture cast orthosis, thermoplastic type casting material, custom-fabricated
L2128	Knee-ankle-foot orthosis, fracture orthosis, femoral fracture cast orthosis, custom-fabricated

L2132	Knee-ankle-foot orthosis, fracture orthosis, femoral fracture cast orthosis, soft, prefabricated, includes fitting and adjustment
L2134	Knee-ankle-foot orthosis, fracture orthosis, femoral fracture cast orthosis, semi-rigid, prefabricated, includes fitting and adjustment
L2136	Knee-ankle-foot orthosis, fracture orthosis, femoral fracture cast orthosis, rigid, prefabricated, includes fitting and adjustment
L2180	Addition to lower extremity fracture orthosis, plastic, shoe insert with ankle joints
L2182	Addition to lower extremity fracture orthosis, drop lock knee joint
L2184	Addition to lower extremity fracture orthosis, limited motion knee joint
L2186	Addition to lower extremity fracture orthosis, adjustable motion knee joint, Lerman type
L2188	Addition to lower extremity fracture orthosis, quadrilateral brim
L2190	Addition to lower extremity fracture orthosis, waist belt
L2192	Addition to lower extremity fracture orthosis, hip joint, pelvic band, thigh flange, and pelvic belt
L2200	Addition to lower extremity, limited ankle motion, each joint
L2210	Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint
L2220	Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint
L2230	Addition to lower extremity, split flat caliper stirrups and plate attachment
L2240	Addition to lower extremity, round caliper and plate attachment
L2250	Addition to lower extremity, foot plate, molded to patient model, stirrup attachment
L2260	Addition to lower extremity, reinforced solid stirrup (Scott-Craig type)
L2265	Addition to lower extremity, long tongue stirrup
L2270	Addition to lower extremity, varus/valgus correction ("T") strap, padded/lined or malleolus pad
L2275	Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined
L2280	Addition to lower extremity, molded inner boot
L2300	Addition to lower extremity, abduction bar, (bilateral hip involvement), jointed adjustable
L2310	Addition to lower extremity, abduction bar – straight
L2320	Addition to lower extremity, non-molded lacer
L2330	Addition to lower extremity, lacer, molded to patient model

L2340	Addition to lower extremity, pre-tibial shell, molded to patient model
L2350	Addition to lower extremity, prosthetic type, (BK) socket, molded to patient model, (used for 'PTB' 'AFO' orthoses)
L2360	Addition to lower extremity, extended steel shank
L2370	Addition to lower extremity, patten bottom
L2375	Addition to lower extremity, torsion control, ankle joint and half solid stirrup
L2380	Addition to lower extremity, torsion control, straight knee joint, each joint
L2385	Addition to lower extremity, straight knee joint, heavy duty, each joint
L2390	Addition to lower extremity, offset knee joint, each joint
L2395	Addition to lower extremity, offset knee joint, heavy duty, each joint
L2397	Addition to lower extremity, orthosis, suspension sleeve
L2405	Addition to knee joint, drop lock, each joint
L2415	Addition to knee lock with integrated release mechanism (bail, cable, or equal), any material, each joint
L2425	Addition to knee joint, disc or dial lock for adjustable knee flexion, each joint
L2430	Addition to knee joint, ratchet lock for active and progressive knee extension, each joint
L2435	Addition to knee joint, polycentric joint, each joint
L2492	Addition to knee joint, lift loop for drop lock ring
L2500	Addition to lower extremity, thigh/weight bearing, gluteal/ischial weight bearing, ring
L2510	Addition to lower extremity, thigh/weight bearing quadrilateral brim, molded to patient model
L2520	Addition to lower extremity, thigh/weight bearing, quadrilateral brim, custom fitted
L2525	Addition to lower extremity, thigh/weight bearing, ischial containment/narrow M-L brim, molded to patient model
L2526	Addition to lower extremity, thigh/weight bearing, ischial containment/narrow M-L brim, custom fitted
L2530	Addition to lower extremity, thigh/weight bearing, lacer, non-molded
L2540	Addition to lower extremity, thigh/weight bearing, lacer, molded to patient model
L2550	Addition to lower extremity, thigh/weight bearing, high roll cuff
L2750	Addition to lower extremity orthosis, plating chrome or nickel, per bar

L2760	Addition to lower extremity orthosis, extension, per extension, per bar (for lineal adjustment for growth)
L2768	Orthotic side bar disconnect device, per bar
L2770	Addition to lower extremity orthosis, any material, per bar or joint
L2780	Addition to lower extremity, non-corrosive finish, per bar
L2785	Addition to lower extremity orthosis, drop lock retainer, each
L2795	Addition to lower extremity orthosis, knee control, full knee cap
L2800	Addition to lower extremity orthosis, knee control, knee cap, medial or lateral pull
L2810	Addition to lower extremity orthosis, knee control, condylar pad
L2820	Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
L2830	Addition to lower extremity orthosis, soft interface for molded plastic, above knee section
L2840	Addition to lower extremity orthosis, tibial length sock, fracture or equal, each
L2850	Addition to lower extremity orthosis, femoral length sock, fracture or equal, each
L2860	Addition to lower extremity joint, knee or ankle, concentric adjustable torsion style mechanism, each
L2999	Lower extremity orthosis, not otherwise specified
L4010	Replace trilateral socket brim
L4020	Replace quadrilateral socket brim, molded to patient model
L4030	Replace quadrilateral socket brim, custom fitted
L4040	Replace molded thigh lacer
L4045	Replace non-molded thigh lacer
L4050	Replace molded calf lacer
L4055	Replace non-molded calf lacer
L4060	Replace high roll cuff
L4070	Replace proximal and distal upright for knee-ankle-foot orthosis
L4080	Replace metal bands knee-ankle-foot orthosis, proximal thigh
L4090	Replace metal bands knee-ankle-foot orthosis -- ankle foot orthosis, calf or distal thigh
L4100	Replace leather cuff knee-ankle-foot orthosis -- ankle foot orthosis, proximal thigh
L4110	Replace leather cuff knee-ankle-foot orthosis -- ankle foot orthosis, calf or distal thigh
L4130	Replace pretibial shell
L4205	Repair of orthotic device, labor component, per 15 minutes

L4210	Repair of orthotic device, repair or replace minor parts
L4392	Replacement, soft interface material, static ankle foot orthosis
L4394	Replacement, soft interface material, foot drop splint
L4396	Static ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, pressure reduction, may be used for minimal ambulation, prefabricated, includes fitting and adjustment
L4398	Foot drop splint, recumbent positioning device, prefabricated, includes fitting and adjustment

HCPCS MODIFIERS

LT	Left side
RT	Right side
GY	Item or service statutorily excluded or does not meet the definition of any Medicare benefit

BENEFIT CATEGORY: Braces (Orthotics)

DEFINITIONS

An orthosis (brace) is a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. An orthosis can be either prefabricated or custom-fabricated.

A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.

A custom-fabricated orthosis is one which is individually made for a specific patient starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as cutting, bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components. It involves more than trimming, bending, or making other modifications to a substantially prefabricated item.

A molded-to-patient-model orthosis is a particular type of custom-fabricated orthosis in which an impression of the specific body part is made (by means of a plaster cast, CAD-CAM technology, etc.) and this impression is then used to make a positive model (of plaster or other material) of the body part. The orthosis is then molded on this positive model.

Ankle-foot orthoses extend well above the ankle (usually to near the top of

the calf) and are fastened around the lower leg above the ankle. These features distinguish them from foot orthotics which are shoe inserts that do not extend above the ankle.

A nonambulatory ankle-foot orthosis may be either an ankle contracture splint or a foot drop splint.

Ankle flexion contracture is a condition in which there is shortening of the muscles and/or tendons that plantarflex the ankle with the resulting inability to bring the ankle to 0 degrees by passive range of motion. (0 degrees ankle position is when the foot is perpendicular to the lower leg.)

A static AFO (L4396) is a prefabricated ankle-foot orthosis which has all of the following characteristics:

1. designed to accommodate an ankle with a plantar flexion contracture up to 45°, and
2. applies a dorsiflexion force to the ankle, and
3. allows pressure reduction, and
4. used by a patient who is minimally ambulatory, or nonambulatory, and
5. has a soft interface.

Foot drop is a condition in which there is weakness and/or lack of use of the muscles that dorsiflex the ankle but there is the ability to bring the ankle to 0 degrees by passive range of motion.

A foot drop splint/recumbent positioning device (L4398) is a prefabricated ankle-foot orthosis which has all of the following characteristics:

1. designed to maintain the foot at a fixed position of 0° (i.e., perpendicular to the lower leg), and
2. not designed to accommodate an ankle with a plantar flexion contracture, and
3. used by a patient who is nonambulatory, and
4. has a soft interface.

COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, "reasonable and necessary" are defined by the following coverage and payment rules.

For an item to be considered for coverage under the Brace benefit category,

it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

AFOs used in nonambulatory patients
A static AFO (L4396) is covered if all of the following criteria are met:

1. plantar flexion contracture of the ankle (ICD-9 diagnosis code 718.47) with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture),
2. reasonable expectation of the ability to correct the contracture,
3. contracture is interfering or expected to interfere significantly with the patient's functional abilities,
4. used as a component of a therapy program which includes active stretching of the involved muscles and/or tendons.

If a static AFO is used for the treatment of a plantar flexion contracture, the pre-treatment passive range of motion must be measured with a goniometer and documented in the medical record. There must be documentation of an appropriate stretching program carried out by professional staff (in a nursing facility) or caregiver (at home).

A static AFO and replacement interface (L4392) is non-covered when it is used solely for the prevention or treatment of a heel pressure ulcer because for these indications it is not used to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body (i.e., it does not meet the definition of a brace).

A static AFO and replacement interface will be denied as not medically necessary if the contracture is fixed. A static AFO and replacement interface will be denied as not medically necessary for a patient with a foot drop but without an ankle flexion contracture. A component of a static AFO that is used to address positioning of the knee or hip will be denied as not medically necessary because the effectiveness of this type of component is not established.

If code L4396 is covered, a replacement interface (L4392) is covered as long as the patient continues to meet indications and other coverage rules for the splint. Coverage of a replacement interface is limited to a maximum of one (1) per 6 months. Additional interfaces will be denied as not medically necessary.

Medicare does not reimburse for a foot drop splint/recumbent positioning device (L4398) or replacement interface (L4394). A foot drop splint/recumbent positioning device and replacement interface is noncovered when it is used solely for the prevention or treatment of a heel pressure ulcer because for these indications it is not used to support a weak or deformed body member or to restrict or eliminate motion in a diseased or

injured part of the body (i.e., it does not meet the definition of a brace). A foot drop splint/recumbent positioning device and replacement interface will be denied as not medically necessary in a patient with foot drop who is nonambulatory because there are other more appropriate treatment modalities. (Refer to Coding Guidelines for coding of orthoses which are worn when a patient is ambulatory.)

AFOs and KAFOs used in ambulatory patients
Ankle-foot orthoses (AFO) described by codes L1900-L1990 and L2106-L2116 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.

Knee-ankle-foot orthoses (KAFO) described by codes L2000-L2039 and L2126-L2136 are covered for ambulatory patients for whom an ankle-foot orthosis is covered and for whom additional knee stability is required.

If the basic coverage criteria for an AFO or KAFO are not met, the orthosis will be denied as not medically necessary.

The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a heel pressure ulcer, it will be denied as noncovered.

AFOs and KAFOs that are molded-to-patient-model or custom-fabricated are covered for ambulatory patients when the basic coverage criteria listed above are met and one of the following criteria are met:

1. The patient could not be fit with a prefabricated AFO, or
2. The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months), or
3. There is a need to control the knee, ankle or foot in more than one plane, or
4. The patient has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury, or
5. The patient has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.

If the specific criteria for a molded-to-patient-model or custom-fabricated orthosis are not met, but the criteria for a prefabricated, custom fitted orthosis are met, payment will be based on the allowance for the least costly medically appropriate alternative.
L coded additions to AFOs and KAFOs (L2180-L2550, L2750-L2830) will be denied as not medically necessary if either the base orthosis is not medically necessary or the specific addition is not medically necessary.

Socks (L2840, L2850) used in conjunction with orthoses are noncovered.

Refer to the Orthopedic Footwear policy for information on coverage of shoes and related items which are an integral part of a brace.

Miscellaneous
Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.

Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.

Replacement of a complete orthosis or component of an orthosis due to loss, significant change in the patient's condition, irreparable wear, or irreparable accidental damage is covered if the device is still medically necessary. The reason for the replacement must be documented in the supplier's record.

The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.

CODING GUIDELINES
Codes L1900, L1904, L1940-L2030, L2036-L2108, L2126-L2128 describe custom-fabricated orthoses. These codes must not be used for prefabricated (i.e., non-custom fabricated) orthoses.

Codes L1900-L1990 and L2106-L2116 are used for an ankle-foot orthosis which is worn when a patient is ambulatory. Code L4396 is used for an ankle-foot orthosis which is worn when a patient is nonambulatory, or minimally ambulatory. Code L4398 is used for an ankle-foot orthosis which is worn when a patient is nonambulatory.

Code L4205 is used for the labor component of repair of a previously provided orthosis except for any labor involved in the replacement of an orthotic component that has a specific L code. It may only be billed for the actual time involved in the repair of an orthosis. It must not be used for any labor involved in the evaluation, fabrication, or fitting of a new or full replacement orthosis. Labor involved in the replacement of an orthotic component that has a specific L code is not separately billable.

Refer to the Orthopedic Footwear policy for information on coding of shoes and related items which are an integral part of a brace.

Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle. Foot orthotics are shoe inserts that do not extend above the ankle. The correct codes for foot orthotics provided for patients without diabetes are L3000-L3090. (Refer to the Orthopedic Footwear policy for more information.) Multiple density foot orthotics used in the management of diabetic foot problems are coded A5509-A5511. (Refer to the Therapeutic Shoes for Diabetics policy for more information.)

Code L2860 is invalid for claim submission to the DMERCs. Claims for prefabricated or custom-fabricated devices that contain a concentric adjustable torsion style mechanism in the knee or ankle joint and that are being used to treat a joint contracture should be coded as E1810 (dynamic adjustable knee extension/flexion device) or E1815 (dynamic adjustable ankle extension/flexion device), respectively. If a concentric adjustable torsion style mechanism in the knee or ankle joint is used in a custom-fabricated orthosis to provide an assist function to joint motion during ambulation, it should be coded as L2999.

A column II code must not be billed in addition to the corresponding column I code when provided at the same time for the same limb.

Column I Code	**Column II Code**
L1900, L1910, L1920, L1980, L1990	L4090, L4110
L2000-L2030	L4070, L4080, L4090, L4100, L4110
L2036, L2037, L2039	L4070
L2188	L4020,L4030
L2320	L4045, L4055
L2330	L4040, L4050
L2335	L4090
L2340	L4130
L2510	L4020
L2520	L4030
L2530	L4045
L2540	L4040
L2550	L4060

The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.

Suppliers should contact the Statistical Analysis Durable Medical

Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for a new or full replacement orthosis which has been signed and dated by the treating physician must be kept on file by the supplier. The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.

The order for a static AFO (L4396) or replacement interface material (L4392) must include the ICD-9 diagnosis code for the underlying condition. The supplier must include this diagnosis code on the claim for the item.

For custom fabricated orthoses, there must be documentation in the supplier's records to support the medical necessity of that type device rather than a prefabricated orthosis. This information does not have to be routinely sent in with the claim, but must be available to the DMERC on request.

If an AFO or KAFO is used solely for the treatment of edema and/or for the prevention or treatment of a heel pressure ulcer, the GY modifier must be added to the base code and any related addition code. If a static AFO (L4396) or foot drop splint/recumbent positioning device (L4398) is used solely for the prevention or treatment of a heel pressure ulcer, the GY modifier must be added to the base code and to the code for the replacement liner (L4392, L4394). When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used -- e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the HA0 record of an electronic claim or attached to a hard copy claim.

A claim for code L2999 must include a narrative description of the item, the brand name and model name/number of the item and a statement defining the medical necessity of the item for the particular patient. A claim for code L4205 must include an explanation of what is being repaired. A claim for code L4210 must include a description of each item that is billed. This information should be entered in the HA0 record of an electronic claim or

attached to a hard copy claim.

All codes for orthoses or repairs of orthoses billed with the same date of service must be submitted on the same claim.

Refer to the Orthopedic Footwear policy for information on documentation requirements for shoes and related items which are an integral part of a brace.

Refer to the Supplier Manual for more information about orders, medical records, and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after April 1, 2002.

This is a revision of a previously published policy.

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Chapter 55 - Spinal Orthoses (TLSO and LSO)

View Attachments

Chapter 55 contains the medical policy for spinal orthoses (TLSO and LSO). Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Spinal Orthoses, TLSO and LSO

HCPCS CODES

The appearance of a code in this section does not necessarily indicate coverage.

L0300	Thoracic-lumbar-sacral-orthoses (TLSO), flexible (dorso-lumbar surgical support)
L0310	TLSO, flexible, dorso-lumbar surgical support, custom fabricated
L0320	TLSO, anterior-posterior control (Taylor type), with apron front
L0321	TLSO, anterior-posterior control, with rigid or semi-rigid posterior panel, prefabricated (includes fitting and adjustment)
L0330	TLSO, anterior-posterior-lateral control (Knight-Taylor type), with apron front
L0331	TLSO, anterior-posterior-lateral control, with rigid or semi-rigid posterior panel, prefabricated (includes fitting and adjustment)
L0340	TLSO, anterior-posterior-lateral-rotary control (Arnold, Magnuson, Steindler types), with apron front
L0350	TLSO, anterior-posterior-lateral-rotary control, flexion compression jacket, custom fitted
L0360	TLSO, anterior-posterior-lateral-rotary control (Arnold, Magnuson, Steindler types), flexion compression jacket, molded to patient model

L0370	TLSO, anterior-posterior-lateral-rotary control, hyperextension (Jewett, Lennox, Baker, Cash types)
L0380	TLSO, anterior-posterior-lateral-rotary control, with extensions
L0390	TLSO, anterior-posterior-lateral control (body jacket) molded to patient model
L0391	TLSO, anterior-posterior-lateral-rotary control, with rigid or semi-rigid posterior panel, prefabricated (includes fitting and adjustment)
L0400	TLSO, anterior-posterior-lateral control (body jacket) molded to patient model, with interface model
L0410	TLSO, anterior-posterior-lateral control (body jacket), two-piece construction, molded to patient model
L0420	TLSO, anterior-posterior-lateral control (body jacket), two-piece construction, molded to patient model, with interface material
L0430	TLSO, anterior-posterior-lateral control (body jacket), with interface material custom fitted
L0440	TLSO, anterior-posterior-lateral control (body jacket), with overlapping front section, spring steel front, custom fitted
L0500	Lumbar-sacral-orthoses (LSO), flexible, (lumbo-sacral surgical support)
L0510	LSO, flexible (lumbo-sacral surgical support), custom fabricated
L0515	LSO, anterior-posterior control, with rigid or semi-rigid posterior panel, prefabricated (includes fitting and adjustment)
L0520	LSO, anterior-posterior-lateral control (Knight, Wilcox types), with apron front
L0530	LSO, anterior-posterior control (Macausland type), with apron front
L0540	LSO, lumbar flexion (Williams flexion type)
L0550	LSO, anterior-posterior-lateral control (body jacket), molded to patient model
L0560	LSO, anterior-posterior-lateral control (body jacket), molded to patient model, with interface material
L0561	LSO, anterior-posterior-lateral control, with rigid or semi-rigid posterior panel, prefabricated (includes fitting and adjustment)
L0565	LSO, anterior-posterior-lateral control (body jacket), custom fitted
L0984	Protective body sock, each
L0986	Addition to spinal orthosis, rigid or semi-rigid abdominal panel, prefabricated

BENEFIT CATEGORY: Braces (Orthotics)

DEFINITIONS

Thoracic-lumbar-sacral orthoses (TLSO) described by codes L0300–L0440 and lumbar-sacral orthoses (LSO) described by codes L0500–L0565 have the following characteristics:

1. Used to immobilize the specified areas of the spine.
2. Intimate fit and generally designed to be worn under clothing.
3. Not specifically designed for patients in wheelchairs.

In addition to (1) and (2), the body jacket type orthoses (L0390, L0400-L0440, L0550, L0560, L0565) are characterized by a rigid plastic shell that encircles the trunk and provides a high degree of immobility.

A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A custom fitted orthosis is a particular type of prefabricated orthosis which has been trimmed, bent, molded(with or without heat), or otherwise modified for use by a specific patient. An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom fabricated orthosis is considered prefabricated.

A custom fabricated orthosis is one which is individually made for a specific patient starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as cutting, bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components. It involves more than trimming, bending, or making other modifications to a substantially prefabricated item.

A molded-to-patient-model orthosis is a particular type of custom fabricated orthosis in which either:

a. An impression of the specific body part is made (usually by means of a plaster cast) and this impression is then used to make a positive model (usually of plaster) of the body part; or
b. Detailed measurements are taken of the patient's torso and are used to modify a positive model (which as been selected from a large library of models) to make it conform to the patient's body shape and dimensions; or
c. An image of the patient's torso is made using computer software which then directs the carving of a positive model.

The orthosis is then molded on this positive model.

Codes L0321, L0331, and L0391 describe TLSOs which have a rigid or semi-rigid posterior panel that extends from the sacrococcygeal junction to the area of the scapular spines. Codes L0515 and L0561 describe LSOs which have a rigid or semi-rigid posterior panel that covers less of the area of the lower back.

Except for code L0370, anterior-posterior control is achieved by a rigid or semi-rigid posterior panel. Except for code L0370, lateral control is achieved by a rigid or semi-rigid panel in the mid-axillary line which is either an integral part of a posterior panel or a separate panel. Except for codes L0350 and L0360, rotary control is achieved by a rigid or semi-rigid panel in the upper chest area which is attached by a rigid connection to a posterior, lateral, or abdominal panel.

COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, "reasonable and necessary" are defined by the following coverage and payment rules.

A thoracic-lumbar-sacral orthosis (L0300-L0440) or lumbar-sacral orthosis (L0500-L0565) is covered when it is ordered for one of the following indications:

1. To reduce pain by restricting mobility of the trunk; or
2. To facilitate healing following an injury to the spine or related soft tissues; or
3. To facilitate healing following a surgical procedure on the spine or related soft tissue; or
4. To otherwise support weak spinal muscles and/or a deformed spine.

A protective body sock (L0984) does not meet the definition of a brace and is noncovered.

Payment for a spinal orthosis is included in the payment to a hospital or SNF if:

1. The orthosis is provided to a patient prior to an inpatient hospital admission or Part A covered SNF stay; and
2. The medical necessity for the orthosis will begin during the hospital or SNF stay (e.g., after spinal surgery.

A claim must not be submitted to the DMERC in this situation.

Payment for a spinal orthosis is also included in the payment to a hospital or SNF if:

1. The orthosis is provided to a patient during an inpatient hospital or Part A covered SNF stay prior to the day of discharge; and
2. The patient uses the item for medically necessary inpatient treatment or rehabilitation.

A claim must not be submitted to the DMERC in this situation.

Payment for a spinal orthosis delivered to a patient in a hospital or SNF is eligible for coverage by the DMERC if:

1. The orthosis is medically necessary for a patient after discharge from a hospital or Part A covered SNF stay; and
2. The orthosis is provided to the patient within two days prior to discharge to home; and
3. The orthosis is not needed for inpatient treatment or rehabilitation, but is left in the room for the patient to take home.

CODING GUIDELINES

Codes L0310, L0320, L0330, L0340, L0360-L0390, L0400-L0420, L0510 and L0520-L0560 describe custom fabricated orthoses. These codes must not be used for prefabricated/custom fitted orthoses.

Code L0986 is used in addition to code L0321, L0331, L0391, L0515, or L0561 if the orthosis has a rigid or semi-rigid abdominal panel.

Codes K0112 (Trunk support device, vest type, with inner frame, prefabricated) and K0113 (Trunk support device, vest type, without inner frame, prefabricated) are invalid for claim submission to the DMERC.

Codes L0315 (TLSO, flexible dorso-lumbar surgical support, elastic type, with rigid posterior panel) and L0317 (TLSO, flexible dorso-lumbar surgical support, hyperextension, elastic type, with rigid posterior panel) are invalid for claim submission to the DMERC. Use code L0321 instead.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home

health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the orthosis which is signed and dated by the treating physician and which clearly describes the type of orthosis ordered must be kept on file by the supplier.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after July 1, 2002.

This is a revision to a previously published policy.

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Chapter 56 - Lower Limb Prostheses

View Attachments

Chapter 56 contains the medical policy for lower limb prostheses. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Lower Limb Prostheses

HCPCS CODES

The appearance of a code in this section does not necessarily indicate coverage.

L5000	Partial foot, shoe insert with longitudinal arch, toe filler
L5010	Partial foot, molded socket, ankle height, with toe filler
L5020	Partial foot, molded socket, tibial tubercle height, with toe filler
L5050	Ankle, Symes, molded socket, SACH foot
L5060	Ankle, Symes, metal frame, molded leather socket, articulated ankle/foot
L5100	Below knee, molded socket, shin, SACH foot
L5105	Below knee, plastic socket, joints and thigh lacer, SACH foot
L5150	Knee disarticulation (or through knee), molded socket, external knee joints, shin, SACH foot
L5160	Knee disarticulation (or through knee), molded socket, bent knee configuration, external knee
L5200	Above knee, molded socket, single axis constant friction knee, shin, SACH foot
L5210	Above knee, short prosthesis, no knee joint ("stubbies"), with foot blocks, no ankle joints, each

L5220	Above knee, short prosthesis, no knee joint ("stubbies"), with articulated ankle/foot, dynamically aligned, each
L5230	Above knee, for proximal femoral focal deficiency, constant friction knee, shin, SACH foot
L5250	Hip disarticulation, Canadian type; molded socket, hip joint, single axis constant friction knee, shin, SACH foot
L5270	Hip disarticulation, tilt table type; molded socket, locking hip joint, single axis constant friction knee, shin, SACH foot
L5280	Hemipelvectomy, Canadian type; molded socket, hip joint, single axis constant friction knee, shin, SACH foot
L5301	Below knee, molded socket, shin, SACH foot, endoskeletal system
L5311	Knee disarticulation (or through knee), molded socket, external knee joints, shin, SACH foot endoskeletal system
L5321	Above knee, molded socket, open end, SACH foot, endoskeletal system, single axis knee
L5331	Hip disarticulation, Canadian type; molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
L5341	Hemipelvectomy, Canadian type; molded socket, endoskeletal system, hip joint, single axis knee, SACH foot
L5400	Immediate post surgical or early fitting, application of initial rigid dressing, including fitting, alignment, suspension, and one cast change, below knee
L5410	Immediate post surgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension, below knee, each additional cast change and realignment
L5420	Immediate post surgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension and one cast change "AK" or knee disarticulation
L5430	Immediate post surgical or early fitting, application of initial rigid dressing, including fitting, alignment and suspension, "AK" or knee disarticulation, each additional cast change and realignment
L5450	Immediate post surgical or early fitting, application of non weight bearing rigid dressing, below knee
L5460	Immediate post surgical or early fitting, application of non weight bearing rigid dressing, above knee
L5500	Initial, below knee 'PTB' type socket, non-alignable system, pylon, no cover, SACH foot, plaster socket, direct formed
L5505	Initial, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot plaster socket, direct formed
L5510	Preparatory, below knee 'PTB' type socket, non-alignable system, pylon, no cover, SACH foot, plaster socket, molded to model

L5530	Preparatory, below knee 'PTB' type socket, non-alignable system, pylon, no cover, SACH foot, thermoplastic or equal, molded to model
L5535	Preparatory, below knee 'PTB' type socket, non-alignable system, pylon, no cover, SACH foot, prefabricated, adjustable open end socket
L5540	Preparatory, below knee 'PTB' type socket, non-alignable system, pylon, no cover, SACH foot, laminated socket, molded to model
L5560	Preparatory, above knee-knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, plaster socket, molded to model
L5570	Preparatory, above knee-knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, thermoplastic or equal, direct formed
L5580	Preparatory, above knee-knee disarticulation ischial level socket, non-alignable system, pylon, no cover, SACH foot, thermoplastic or equal, molded to model
L5585	Preparatory, above knee-knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, prefabricated adjustable open end socket
L5590	Preparatory, above knee-knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, laminated socket, molded to model
L5595	Preparatory, hip disarticulation-hemipelvectomy, pylon, no cover, SACH foot, thermoplastic or equal, molded to patient model
L5600	Preparatory, hip disarticulation-hemipelvectomy, pylon, no cover, SACH foot, laminated socket, molded to patient model
L5610	Addition to lower extremity, endoskeletal system, above knee, hydracadence system
L5611	Addition to lower extremity, endoskeletal system, above knee-knee disarticulation, 4-bar linkage with friction swing phase control
L5613	Addition to lower extremity, endoskeletal system, above knee-knee disarticulation, 4-bar linkage, with hydraulic swing phase control
L5614	Addition to lower extremity, exoskeletal system, above knee-knee disarticulation, 4 bar linkage with pneumatic swing phase control
L5616	Addition to lower extremity, endoskeletal system, above knee, universal multiplex system, friction swing phase control
L5617	Addition to lower extremity, quick change self-aligning unit, above knee or below knee, each
L5618	Addition to lower extremity, test socket, Symes
L5620	Addition to lower extremity, test socket, below knee

L5622	Addition to lower extremity, test socket, knee disarticulation
L5624	Addition to lower extremity, test socket, above knee
L5626	Addition to lower extremity, test socket, hip disarticulation
L5628	Addition to lower extremity, test socket, hemipelvectomy
L5629	Addition to lower extremity, below knee, acrylic socket
L5630	Addition to lower extremity, Symes type, expandable wall socket
L5631	Addition to lower extremity, above knee or knee disarticulation, acrylic socket
L5632	Addition to lower extremity, Symes type, "PTB" brim design socket
L5634	Addition to lower extremity, Symes type, posterior opening (Canadian) socket
L5636	Addition to lower extremity, Symes type, medial opening socket
L5637	Addition to lower extremity, below knee, total contact
L5638	Addition to lower extremity, below knee, leather socket
L5639	Addition to lower extremity, below knee, wood socket
L5640	Addition to lower extremity, knee disarticulation, leather socket
L5642	Addition to lower extremity, above knee, leather socket
L5643	Addition to lower extremity, hip disarticulation, flexible inner socket, external frame
L5644	Addition to lower extremity, above knee, wood socket
L5645	Addition to lower extremity, below knee, flexible inner socket, external frame
L5646	Addition to lower extremity, below knee, air cushion socket
L5647	Addition to lower extremity, below knee, suction socket
L5648	Addition to lower extremity, above knee, air cushion socket
L5649	Addition to lower extremity, ischial containment/narrow M-L socket
L5650	Addition to lower extremity, total contact, above knee or knee disarticulation socket
L5651	Addition to lower extremity, above knee, flexible inner socket, external frame
L5652	Addition to lower extremity, suction suspension, above knee or knee disarticulation socket
L5653	Addition to lower extremity, knee disarticulation, expandable wall socket
L5654	Addition to lower extremity, socket insert, Symes, (Kemblo, Pelite, Aliplast, Plastazote or equal)
L5655	Addition to lower extremity, socket insert, below knee (Kemblo, Pelite, Aliplast, Plastazote or equal)

L5658	Addition to lower extremity, socket insert, above knee (Kemblo, Pelite, Aliplast, Plastazote or equal)
L5660	Addition to lower extremity, socket insert, Symes, silicone gel or equal
L5661	Addition to lower extremity, socket insert, multi-durometer Symes
L5662	Addition to lower extremity, socket insert, below knee, silicone gel or equal
L5663	Addition to lower extremity, socket insert, knee disarticulation, silicone gel or equal
L5664	Addition to lower extremity, socket insert, above knee, silicone gel or equal
L5665	Addition to lower extremity, socket insert, multi-durometer, below knee
L5666	Addition to lower extremity, below knee, cuff suspension
L5668	Addition to lower extremity, below knee, molded distal cushion
L5670	Addition to lower extremity, below knee, molded supracondylar suspension ("PTS" or similar)
L5671	Addition to lower extremity, below knee/above knee, suspension locking mechanism (shuttle, lanyard, or equal), excludes socket insert
L5672	Addition to lower extremity, below knee, removable medial brim suspension
L5674	Addition to lower extremity, below knee, any material, each
L5675	Addition to lower extremity, below knee, any material, heavy duty, each
L5676	Additions to lower extremity, below knee, knee joints, single axis, pair
L5677	Additions to lower extremity, below knee, knee joints, polycentric, pair
L5678	Additions to lower extremity, below knee, joint covers, pair
L5680	Addition to lower extremity, below knee, thigh lacer, non-molded
L5682	Addition to lower extremity, below knee, thigh lacer, gluteal/ischial, molded
L5684	Addition to lower extremity, below knee, fork strap
L5686	Addition to lower extremity, below knee, back check (extension control)
L5688	Addition to lower extremity, below knee, waist belt, webbing
L5690	Addition to lower extremity, below knee, waist belt, padded and lined
L5692	Addition to lower extremity, above knee, pelvic control belt, light

L5694	Addition to lower extremity, above knee, pelvic control belt, padded and lined
L5695	Addition to lower extremity, above knee, pelvic control, sleeve suspension, neoprene or equal, each
L5696	Addition to lower extremity, above knee or knee disarticulation, pelvic joint
L5697	Addition to lower extremity, above knee or knee disarticulation, pelvic band
L5698	Addition to lower extremity, above knee or knee disarticulation, silesian bandage
L5699	All lower extremity prostheses, shoulder harness
L5700	Replacement, socket, below knee, molded to patient model
L5701	Replacement, socket, above knee/knee disarticulation including attachment plate, molded to patient model
L5702	Replacement, socket, hip disarticulation, including hip joint, molded to patient model
L5704	Custom shaped protective cover, below knee
L5705	Custom shaped protective cover, above knee
L5706	Custom shaped protective cover, knee disarticulation
L5707	Custom shaped protective cover, hip disarticulation
L5710	Addition, exoskeletal knee-shin system, single axis, manual lock
L5711	Addition, exoskeletal knee-shin system, single axis, manual lock, ultra-light material
L5712	Addition, exoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)
L5714	Addition, exoskeletal knee-shin system, single axis, variable friction swing phase control
L5716	Addition, exoskeletal knee-shin system, polycentric, mechanical stance phase lock
L5718	Addition, exoskeletal knee-shin system, polycentric, friction swing and stance phase control
L5722	Addition, exoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control
L5724	Addition, exoskeletal knee-shin system, single axis, fluid swing phase control
L5726	Addition, exoskeletal knee-shin system, single axis, external joints fluid swing phase control
L5728	Addition, exoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5780	Addition, exoskeletal knee-shin system, single axis, pneumatic/hydra pneumatic swing phase control
L5785	Addition, exoskeletal system, below knee, ultra-light material

	(titanium, carbon fiber or equal)
L5790	Addition, exoskeletal system, above knee, ultra-light material (titanium, carbon fiber or equal)
L5795	Addition, exoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal)
L5810	Addition, endoskeletal knee-shin system, single axis, manual lock
L5811	Addition, endoskeletal knee-shin system, single axis, manual lock, ultra-light material
L5812	Addition, endoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)
L5814	Addition, endoskeletal knee-shin system, polycentric, hydraulic swing phase control, mechanical stance phase lock
L5816	Addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock
L5818	Addition, endoskeletal knee-shin system, polycentric, friction swing, and stance phase control
L5822	Addition, endoskeletal knee-shin system, single axis, pneumatic swing, friction stance phase control
L5824	Addition, endoskeletal knee-shin system, single axis, fluid swing phase control
L5826	Addition, endoskeletal knee-shin system, single axis, hydraulic swing phase control, with miniature high activity frame
L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5830	Addition, endoskeletal knee-shin system, single axis, pneumatic/swing phase control
L5840	Addition, endoskeletal knee-shin system multiaxial, pneumatic swing phase control
L5845	Addition, endoskeletal, knee-shin system, stance flexion feature, adjustable
L5846	Addition, endoskeletal, knee-shin system, microprocessor control feature, swing phase only
L5847	Addition, endoskeletal, knee-shin system, microprocessor control feature, stance phase
L5850	Addition, endoskeletal system, above knee or hip disarticulation, knee extension assist
L5855	Addition, endoskeletal system, hip disarticulation, mechanical hip extension assist
L5910	Addition, endoskeletal system, below knee, alignable system
L5920	Addition, endoskeletal system, above knee or hip disarticulation, alignable system
L5925	Addition, endoskeletal system, above knee, knee disarticulation

	or hip disarticulation, manual lock
L5930	Addition, endoskeletal system, high activity knee control frame
L5940	Addition, endoskeletal system, below knee, ultra-light material (titanium, carbon fiber or equal)
L5950	Addition, endoskeletal system, above knee, ultra-light material (titanium, carbon fiber or equal)
L5960	Addition, endoskeletal system, hip disarticulation, ultra-light material (titanium, carbon fiber or equal)
L5962	Addition, endoskeletal system, below knee flexible protective outer surface covering system
L5964	Addition, endoskeletal system, above knee flexible protective outer surface covering system
L5966	Addition, endoskeletal system, hip disarticulation, flexible protective outer surface covering system
L5968	Addition to lower limb prosthesis, multiaxial ankle with swing phase active dorsiflexion feature
L5970	All lower extremity prostheses, foot, external keel, SACH foot
L5972	All lower extremity prostheses, flexible keel foot (Safe, Sten, Bock dynamic or equal)
L5974	All lower extremity prostheses, foot, single axis ankle/foot
L5975	All lower extremity prostheses, combination single axis ankle and flexible keel foot
L5976	All lower extremity prostheses, energy storing foot (Seattle Carbon Copy II or equal)
L5978	All lower extremity prostheses, foot, multiaxial ankle/foot
L5979	All lower extremity prostheses, multiaxial ankle, dynamic response foot, one piece system
L5980	All lower extremity prostheses, flex foot system
L5981	All lower extremity prostheses, flex-walk system or equal
L5982	All exoskeletal lower extremity prostheses, axial rotation unit
L5984	All endoskeletal lower extremity prostheses, axial rotation unit
L5985	All endoskeletal lower extremity prostheses, dynamic prosthetic pylon
L5986	All lower extremity prostheses, multi-axial rotation unit ("MCP" or equal)
L5987	All lower extremity prostheses, shank foot system with vertical loading pylon
L5988	Addition to lower limb prosthesis, vertical shock reducing pylon feature
L5989	Addition to lower extremity prosthesis, endoskeletal system, pylon with integrated electronic force sensors

L5990	Addition to lower extremity prosthesis, user adjustable heel height
L5999	Lower extremity prosthesis, not otherwise specified
L7510	Repair of prosthetic device, repair or replace minor parts
L7520	Repair prosthetic device, labor component, per 15 minutes
L8400	Prosthetic sheath, below knee, each
L8410	Prosthetic sheath, above knee, each
L8417	Prosthetic sheath/sock, including a gel cushion layer, below knee or above knee, each
L8420	Prosthetic sock, multiple ply, below knee, each
L8430	Prosthetic sock, multiple ply, above knee, each
L8440	Prosthetic shrinker, below knee, each
L8460	Prosthetic shrinker, above knee, each
L8470	Prosthetic sock, single ply, fitting, below knee, each
L8480	Prosthetic sock, single ply, fitting, above knee, each
L8490	Addition to prosthetic sheath/sock, air seal suction retention system

HCPCS MODIFIERS

K0	Lower limb extremity prosthesis functional Level 0 - Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility
K1	Lower extremity prosthesis functional Level 1 - Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
K2	Lower extremity prosthesis functional Level 2 - Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
K3	Lower extremity prosthesis functional Level 3 - Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4	Lower extremity prosthesis functional Level 4 - Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

BENEFIT CATEGORY: Artificial Limbs

DEFINITIONS
A functional level is a measurement of the capacity and potential of the patient to accomplish his/her expected post-rehabilitation, daily function. The functional classification is used by the DMERC to establish the medical necessity only of prosthetic knees, feet and ankles.

An adjustment is any modification to the prosthesis due to a change in the patient's condition or to improve the function of the prosthesis.
A repair is a restoration of the prosthesis to correct problems due to wear or damage.

A replacement is the removal and substitution of a component of a prosthesis that has a HCPCS definition.

COVERAGE AND PAYMENT RULES
For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, "reasonable and necessary" are defined by the following coverage and payment rules.

A lower limb prosthesis is covered when the patient:

1. Will reach or maintain a defined functional state within a reasonable period of time; *and*
2. Is motivated to ambulate

Functional Levels
A determination of the medical necessity for certain components/additions to the prosthesis is based on the patient's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:

a. the patient's past history (including prior prosthetic use if applicable); and
b. the patient's current condition including the status of the residual limb and the nature of other medical problems and; and
c. the patient's desire to ambulate.

Clinical assessments of patient rehabilitation potential should be based on the following classification levels:

Level 0:	Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
Level 1:	Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
Level 2:	Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
Level 3:	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
Level 4:	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

The records should document the patient's current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case. The DMERC recognizes within the functional classification hierarchy that bilateral amputees often cannot be strictly bound by functional level classifications.

General

Prostheses are covered when furnished incident to physicians' services or on a physician's order. Accessories (e.g., stump stockings for the residual limb, harness (including replacements)) are also covered when these appliances aid in or are essential to the effective use of the artificial limb.

The following items are included in the reimbursement for a prosthesis and, therefore, are not separately billable to Medicare under the prosthetic benefit:

- Evaluation of the residual limb and gait
- Fitting of the prosthesis
- Cost of base component parts and labor contained in HCPCS base codes
- Repairs due to normal wear or tear within 90 days of delivery
- Adjustments of the prosthesis or the prosthetic component made when fitting the prosthesis or component and for 90 days from the date of delivery when the adjustments **are not** necessitated by changes in the residual limb or the patient's functional abilities.

Payment for a prosthesis is included in the payment to a hospital or SNF if:

1. The prosthesis is provided to a patient during an inpatient hospital or Part A covered SNF stay prior to the day of discharge; and
2. The patient uses the prosthesis for medically necessary inpatient treatment or rehabilitation.

A claim must not be submitted to the DMERC in this situation.

Payment for a prosthesis delivered to a patient in a hospital or SNF is eligible for coverage by the DMERC if:

1. The prosthesis is medically necessary for a patient after discharge from a hospital or Part A covered SNF stay; and
2. The prosthesis is provided to the patient within two days prior to discharge to home; and
3. The prosthesis is not needed for inpatient treatment or rehabilitation, but is left in the room for the patient to take home.

When an initial below knee prosthesis (L5500) or a preparatory below knee prosthesis (L5510-L5530, L5540) prostheses is provided, prosthetic substitutions and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5629, L5638, L5639, L5646, L5647, L5785, L5962, and L5980 which will be denied as not medically necessary. When a below knee preparatory prefabricated prosthesis (L5535) is provided, prosthetic substitutions and/or additions of procedures are covered in accordance with the functional level assessment except for codes L5620, L5629, L5645, L5646, L5670, and L5676 which will be denied as not medically necessary.

When an above knee initial prosthesis (L5505) or an above knee preparatory (L5560-L5580, L5590-L5600) prostheses is provided, prosthetic substitution and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5610, L5631, L5640, L5642, L5644, L5648, L5980, L5710-L5780, and L5790-L5795, which will be denied as not medically necessary. When an above knee preparatory prefabricated prosthesis (L5585) is provided, prosthetic substitution and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5624, L5631, L5648, L5651, L5652, L5964, and L5966 which will be denied as not medically necessary.

In the following sections, the determination of coverage for selected prostheses and components with respect to potential functional levels represents the usual case. Exceptions will be considered in an individual case if additional documentation is included which justifies the medical necessity. Prostheses will be denied as not medically necessary if the patient's potential functional level is 0.

Feet

A determination of the type of foot for the prosthesis will be made by the

treating physician and/or the prosthetist based upon the functional needs of the patient. Basic lower extremity prostheses include a SACH foot. Other prosthetic feet are considered for coverage based upon functional classification.

An external keel, SACH foot (L5970) or single axis ankle/foot (L5974) is covered for patients whose functional level is 1 or above.

A flexible-keel foot (L5972) or multiaxial ankle/foot (L5978) is covered for patients whose functional level is 2 or above.

A flex foot system (L5980), energy storing foot (L5976), multiaxial ankle/foot, dynamic response (L5979), or flex-walk system or equal (L5981) is covered for patients whose functional level is 3 or above.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of foot. This information must be retained in the physician's or prosthetist's files.

Knees
A determination of the type of knee for the prosthesis will be made by the treating physician and/or the prosthetist based upon the functional needs of the patient. Basic lower extremity prostheses include a single axis, constant friction knee. Prosthetic knees are considered for coverage based upon functional classification.

A fluid or pneumatic knee (L5610, L5613, L5614, L5722-L5780, L5822-L5840) is covered for patients whose functional level is 3 or above.

Other knee systems (L5611, L5616, L5710-L5718, L5810-L5818) are covered for patients whose functional level is 1 or above.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic design feature of a given type of knee. This information must be retained in the physician's or prosthetist's files.

Ankles
An axial rotation units (L5982-L5986) is covered for patients whose functional level is 2 or above.

Sockets
Test (diagnostic) sockets for immediate prostheses (L5400-L5460) are not medical necessary.

No more than 2 test (diagnostic) sockets for an individual prosthesis are medically necessary without additional documentation.

No more than two of the same socket inserts (L5654-L5665) are allowed per individual prosthesis at the same time.

Socket replacements are considered medically necessary if there is adequate documentation of functional and/or physiological need. The DMERC recognizes that there are situations where the explanation includes but is not limited to: changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive patient weight or prosthetic demands of very active amputees.

Adjustment, Repairs, and Component Replacement
Routine periodic servicing, such as testing, cleaning, and checking of the prosthesis is non-covered. Adjustments to a prosthesis required by wear or by change in the patient's condition are covered under the initial physician's order for the prosthesis for the life of the prosthesis.

Repairs to a prosthesis are covered when necessary to make the prosthesis functional. If the expense for repairs exceeds the estimated expense of purchasing another entire prosthesis, no payments can be made for the amount of the excess. Maintenance which may be necessitated by manufacturer's recommendations or the construction of the prosthesis and must be performed by the prosthetist is covered as a repair.

Replacement of a prosthesis or prosthetic component is covered if the treating physician orders a replacement device or part because of any of the following:

1. A change in the physiological condition of the patient; or
2. Irreparable wear of the device or a part of the device; or
3. The condition of the device, or part of the device, requires repairs and the cost of such repairs would be more than 60% of the cost of a replacement device, or of the part being replaced.

Replacement of a prosthesis or prosthetic components required because of loss or irreparable damage may be reimbursed without a physician's order when it is determined that the prosthesis as originally ordered still fills the patient's medical needs.

CODING GUIDELINES
Adjustments and repairs are billed as a labor charge using HCPCS code L7520 (one unit of service representing 15 minutes of labor time). Documentation must exist in the supplier's records indicating the precise adjustments and/or repairs performed and actual time involved. The time reported for L7520 must only be for laboratory repair time and associated prosthetic evaluation. Evaluation not associated with repair or adjustment is non-covered and must not be coded with L7520. The time for patient evaluation, gait instruction, and other general education should not be reported with code L7520.

The L7510 code is used to bill for any "minor" materials (those without HCPCS codes) used to achieve the adjustment and/or repair.

Replacement of components (except sockets) is billed using the code for the component with the addition of the RP modifier. Socket replacements are identified by the codes L5700-L5702. Since these codes are defined as a replacement, the modifier RP must not be used. The submitted charge for replacements includes both the cost of the component and the labor associated with the removal, replacement, and finishing of that component. Labor associated with replacement must not be reported using code L7520.

Code L5671 includes both the part of the suspension locking mechanism that is integrated into the prosthesis socket and the pin(s), lanyard, or other component which is attached to the socket insert. L5671 does not include the socket insert itself. The socket inserts used in conjunction with a suspension locking mechanism are billed with codes L5660, L5662. L5663, or L5664, as appropriate. These codes include socket inserts with or without a distal umbrella adapter for attaching the pin or lanyard of the locking mechanism.

The right (RT) and left (LT) modifiers should be used with prosthesis codes. When the same code for prostheses, sockets, or components for bilateral amputees are billed on the same date of service, the items (RT and LT) will be entered on the same line of the claim using the LTRT modifiers and billed with 2 units of service.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the prosthesis including all components which is signed and dated by the treating physician must be kept on file by the prosthetist. Adjustments and repairs of prostheses and prosthetic components are covered under this original order. Claims involving replacement of a prosthesis or major component (foot, ankle, knee, socket) necessitated by wear or a change in the patient's condition must be supported by a new physician's order. If replacement of a prosthesis or prosthetic component is required because of loss or irreparable damage, reimbursement may be made without a new physician's order if it is determined that the prosthesis as originally ordered, considering the time since it was furnished, still fills the patient's medical need.

The prosthetist must retain documentation of the prosthesis or prosthetic

component replaced, the reason for replacement, and a description of the labor involved irrespective of the time since the prosthesis was provided to the beneficiary. When replacement of the entire prosthesis or socket is billed, the claim must be accompanied by an explanation of the medical necessity of the replacement. The DMERC recognizes that there are situations where the explanation includes but is not limited to: changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive patient weight or prosthetic demands of very active amputees.

When submitting a prosthetic claim to the DMERC, the billed code for knees, feet and ankles (HCPCS codes L5610-L5616, L5710-L5780, L5810-L5840, L5970-L5981, L5982-L5986) components must be submitted with modifiers K0-K4, indicating the expected patient functional level. This expectation of functional ability information must be clearly documented and retained in the prosthetist's records. The simple entry of a K modifier in those records is not sufficient. There must be information about the patient's history and current condition which supports the designation of the functional level by the prosthetist.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: Claims for dates of service on or after April 1, 2002.

This is a revision of a previously published policy.

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Chapter 57 - Therapeutic Shoes for Diabetics

View Attachments

Chapter 57 contains the medical policy for therapeutic shoes for diabetics. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Therapeutic Shoes for Diabetics

HCPCS CODES

The appearance of a code in this section does not necessarily indicate coverage.

A5500	For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multi-density insert(s), per shoe
A5501	For diabetics only, fitting (including follow-up), custom preparation and supply of shoe molded from cast(s) of patient's foot (custom molded shoe), per shoe
A5503	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with roller or rigid rocker bottom, per shoe
A5504	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with wedge(s), per shoe
A5505	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with metatarsal bar, per shoe
A5506	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with off-set heel (s), per shoe

A5507	For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe, per shoe
A5508	For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom-molded shoe, per shoe
A5509	For diabetics only, direct formed, molded to foot with external heat source (i.e., heat gun) multiple density insert(s), prefabricated, per shoe
A5510	For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert (s), prefabricated, per shoe
A5511	For diabetics only, custom-molded from model of patient's foot, multiple density insert(s), custom-fabricated, per shoe

HCPCS MODIFIERS

KX	Specific required documentation on file
LT	Left side
RT	Right side

BENEFIT CATEGORY: Therapeutic Shoes for Diabetics

DEFINITIONS

A depth shoe (A5500) is one that 1) has a full length, heel-to-toe filler that when removed provides a minimum of 3/16" of additional depth used to accommodate custom-molded or customized inserts; 2) is made from leather or other suitable material of equal quality; 3) has some form of shoe closure and 4) is available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoe according to the American standard last sizing schedule or its equivalent. (The American last sizing schedule is the numerical shoe sizing system used for shoes in the United States.) This includes a shoe with or without an internally seamless toe.

A custom-molded shoe (A5501) is one that 1) is constructed over a positive model of the patient's foot, 2) is made from leather or other suitable material of equal quality, 3) has removable inserts that can be altered or replaced as the patient's condition warrants and 4) has some form of shoe closure. This includes a shoe with or without an internally seamless toe.

A diabetic shoe insert is a total contact, multiple density, removable inlay that is directly molded to the patient's foot or a model of the patient's foot and that is made of a suitable material with regard to the patient's condition. For code A5509, molding of the insert must be accomplished by an external heat source (e.g., oven or heat gun).

Rigid rocker bottoms (A5503) are exterior elevations with apex position for

51 percent to 75 percent distance measured from the back end of the heel. The apex is a narrowed or pointed end of an anatomical structure. The apex must be positioned behind the metatarsal heads and tapering off sharply to the front tip of the sole. Apex height helps to eliminate pressure at the metatarsal heads. Rigidity is ensured by the steel in the shoe. The heel of the shoe tapers off in the back in order to cause the heel to strike in the middle of the heel.

Roller bottoms (sole or bar) (A5503) are the same as rocker bottoms, but the heel is tapered from the apex to the front tip of the sole.

Wedges (posting) (A5504) are either of hind foot, fore foot, or both and may be in the middle or to the side. The function is to shift or transfer weight bearing upon standing or during ambulation to the opposite side for added support, stabilization, equalized weight distribution, or balance.

Metatarsal bars (A5505) are exterior bars which are placed behind the metatarsal heads in order to remove pressure from the metatarsal heads. The bars are of various shapes, heights, and construction depending on the exact purpose.

Offset heel (A5506) is a heel flanged at its base either in the middle, to the side, or a combination, that is then extended upward to the shoe in order to stabilize extreme positions of the hind foot.

A deluxe feature (A5508) does not contribute to the therapeutic function of the shoe. It may include, but is not limited to style, color, or type of leather.

The **Certifying Physician** provides the medical care for the beneficiary's diabetic condition. The certifying physician must be an M.D. or D.O., and may not be a podiatrist.

The **Prescribing Physician** actually writes the order for the therapeutic shoe, modifications and inserts. The prescribing physician may be a podiatrist, M.D, or D.O.

The **Supplier** is the person or entity that actually furnishes the shoe, modification, and/or insert to the beneficiary and that bills Medicare. The supplier may be a podiatrist, pedorthist, orthotist, prosthetist, or other qualified individual. The **Prescribing** physician may be the supplier. The **Certifying** physician may **only** be the supplier if the certifying physician is practicing in a defined rural area or a defined health professional shortage area.

COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must (1) be eligible for a defined Medicare Benefit Category, (2) be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member, and (3) meet all other applicable Medicare

statutory and regulatory requirements. For the items addressed in this regional medical review policy, "reasonable and necessary" are defined by the following coverage and payment rules.

Diabetic shoes, inserts and/or modifications to the shoes are covered if the following criteria are met:

1. The patient has diabetes mellitus (ICD-9-CM diagnosis codes 250.00-250.93); and
2. The patient has one or more of the following conditions:
   a. Previous amputation of the other foot, or part of either foot, or
   b. History of previous foot ulceration of either foot, or
   c. History of pre-ulcerative calluses of either foot, or
   d. Peripheral neuropathy with evidence of callus formation of either foot, or
   e. Foot deformity of either foot, or
   f. Poor circulation in either foot; and
3. The certifying physician who is managing the patient's systemic diabetes condition has certified that indications (1) and (2) are met and that he/she is treating the patient under a comprehensive plan of care for his/her diabetes and that the patient needs diabetic shoes.

For patients meeting these criteria, coverage is limited to one of the following within one calendar year:

1. One pair of custom molded shoes (A5501) (which includes inserts provided with these shoes) and 2 additional pairs of inserts (A5509 or A5511); or
2. One pair of depth shoes (A5500) and 3 pairs of inserts (A5509 or A5511) (not including the non-customized removable inserts provided with such shoes).

Separate inserts may be covered and dispensed independently of diabetic shoes if the supplier of the shoes verifies in writing that the patient has appropriate footwear into which the insert can be placed. This footwear must meet the definitions found in this policy for depth shoes or custom-molded shoes.

Items represented by code A5510 reflect compression molding to the patient's foot over time through the heat and pressure generated by wearing a shoe with the insert present. Since these inserts are not considered total contact at the time of dispensing, they do not meet the requirements of the benefit category and will be denied as non-covered.

Inserts used in non-covered shoes are non-covered.

A custom molded shoe (A5501) is covered when the patient has a foot deformity which cannot be accommodated by a depth shoe. The nature and severity of the deformity must be well documented in the supplier's records and may be requested by the DMERC. If there is insufficient justification for a custom molded shoe but the general coverage criteria are met, payment will be based on the allowance for the least costly medically appropriate alternative, A5500.

A modification of a custom molded or depth shoe will be covered as a substitute for an insert. Although not intended as a comprehensive list, the following are the most common shoe modifications: rigid rocker bottoms (A5503), roller bottoms (A5503), wedges (A5504), metatarsal bars (A5505), or offset heels (A5506). Other modifications to diabetic shoes (A5507) include, but are not limited to, flared heels.

Deluxe features of diabetic shoes (A5508) will be denied as noncovered.

Shoes, inserts, and/or modifications that are provided to patients who do not meet the coverage criteria will be denied as non-covered. When codes are billed without a KX modifier (see Documentation section), they will be denied as non-covered.

The particular type of footwear (shoes, inserts, modifications) which is necessary must be prescribed by a podiatrist or other qualified physician, knowledgeable in the fitting of diabetic shoes and inserts. The footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, orthotist or prosthetist. The certifying physician (i.e., the physician who manages the systemic diabetic condition) may not furnish the footwear unless he/she practices in a defined rural area or a defined health professional shortage area. The prescribing physician (podiartrist or other qualified physician) can be the supplier (i.e., the one who furnishes the footwear).

There is no separate payment for the fitting of the shoes, inserts or modifications or for the certification of need or prescription of the footwear. Unrelated evaluation and management services by the physician are processed by the local carrier.

CODING GUIDELINES

Code A5507 is only to be used for not otherwise specified therapeutic modifications to the shoe or for repairs to a diabetic shoe(s).

Deluxe features must be coded using code A5508.

Codes for inserts or modifications (A5503-A5511) may only be used for items related to diabetic shoes (A5500, A5501). They should not be used for items related to footwear coded with codes L3215-L3253. Inserts and modifications used with L coded footwear must be coded using L codes

(L3000-L3649).

When a single shoe, insert or modification is provided, the appropriate modifier, right (RT) or left (LT), must be used. If a pair is provided, report as two (2) units of service on the claim -- the RT or LT modifiers should not be used.

Inserts for missing toes or partial foot amputation should be coded L5000 or L5999, whichever is applicable.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (**SADMERC**) for guidance on the correct coding of these items.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the shoes, inserts or modifications which has been signed and dated by the prescribing physician must be kept on file by the supplier. If the prescribing physician is the supplier, a separate order is not required, but the item provided must be clearly noted in the patient's record. A new order is not required for the replacement of an insert or modification within one year of the order on file. However, the supplier's records should document the reason for the replacement. A new order is required for the replacement of any shoe. A new order is also required for the replacement of an insert or modification more than one year from the most recent order on file.

The supplier must obtain a signed statement from the certifying physician specifying that the patient has diabetes mellitus, has one of conditions 2a-2f listed in the policy, is being treated under a comprehensive plan of care for his/her diabetes, and needs diabetic shoes. The certifying physician must be either an M.D. or D.O. and may not be a podiatrist. The Statement of Certifying Physician for Therapeutic Shoes developed by the DMERC is recommended (whatever form is used must contain all of the elements contained on the attached recommended form). This statement may be completed by the prescribing physician or supplier but must be reviewed for accuracy of the information and signed by the certifying physician to indicate agreement. A new Certification Statement is required for a shoe, insert or modification provided more than one year from the most recent Certification Statement on file. If the supplier has a current signed statement on file that indicates that the coverage criteria described above have been met, then a KX modifier must be added to the code. A diagnosis code for

diabetes (ICD-9 250.00-250.93) should be entered on the claim.

If code A5507 is submitted, the claim must contain a narrative description of the modification or feature provided.

The prescribing physician's name and UPIN number must be listed in Blocks 17 and 17a of the CMS-1500 form or the electronic equivalent.

Refer to the Supplier Manual for more information on orders, medical records and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after July 1, 2002.

This is a revision of a previously published policy.

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